

\*\*\*\*\* NOTICE OF GRANT AWARD \*\*\*\*\*  
RESEARCH PROJECT COOPERATIVE AGREEMENT  
Department of Health and Human Services  
National Institutes of Health  
NATIONAL CANCER INSTITUTE  
\*\*\*\*\*

Issue Date: 09/08/2003



Grant Number: 5 U01 CA033193-22  
Principal Investigator: Cogliano, Vincent James  
Project Title: EVALUATION OF CARCINOGENIC RISKS TO HUMANS

DIRECTOR, ADMIN & FINANCE  
INTER AGENCY FOR RES ON CANCER  
150 COURS ALBERT THOMAS  
69372 LYON CEDEX 08  
FRANCE

Budget Period: 09/01/2003 - 08/31/2004  
Project Period: 09/01/1985 - 08/31/2005

ar Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$482,794 (see 'Award Calculation' in Section I) to WORLD HLTH ORG INTL AGCY RES ON CANCER in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 & 6306 and is subject to terms and conditions referenced below.

Acceptance of this award including the Terms and Conditions is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Award recipients are responsible for reporting inventions derived or reduced to practice in the performance of work under this grant. Rights to inventions vest with the grantee organization provided certain requirements are met and there is acknowledgement of NIH support. In addition, recipients must ensure that patent and license activities are consistent with their responsibility to make unique research resources developed under this award available to the scientific community, in accordance with NIH policy. For additional information, please visit <http://www.iedison.gov>.

If you have any questions about this award, please contact the individual(s) referenced in the information below.

Sincerely yours,

Joy Kearse  
Grants Management Officer  
NATIONAL CANCER INSTITUTE

See additional information below

SECTION I - AWARD DATA - 5 U01 CA033193-22

AWARD CALCULATION (U.S. Dollars):

Salaries and Wages	\$317,259
Fringe Benefits	\$105,872
Personnel Costs	\$423,131
Consultant Services	\$37,461
Travel Costs	\$3,122
Other Costs	\$151,628
Federal Direct Costs	\$615,342
Federal F&A Costs	\$79,994
APPROVED BUDGET	\$695,336
Less Unobligated Balance	\$212,542
TOTAL FEDERAL AWARD AMOUNT	\$482,794

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project, is as follows.

23 (b)(5)

ASCAL INFORMATION:

CFDA Number: 93.393

EIN: 1900210016A1

Document Number: U1CA33193E

IC/ CAN / FY2003 / FY2004

CA/8423126 / 482,794 / (b)(5)

NIH ADMINISTRATIVE DATA:

PCC: 38CG3126 / OC: 41.4P /Processed: KEARSEJ 030904 0134

SECTION II - PAYMENT/HOTLINE INFORMATION - 5 U01 CA033193-22

For Payment and HHS Office of Inspector General Hotline Information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III - TERMS AND CONDITIONS - 5 U01 CA033193-22

This award is based on the application submitted to, and as approved by, the NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in this Notice of Grant Award.
- The restrictions on the expenditure of federal funds in appropriations acts, to the extent those restrictions are pertinent to the award.
- 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(see NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

Treatment of Program Income:  
Additional Costs

INFORMATION This award is issued as a Cooperative Agreement, a financial assistance mechanism which requires cooperation between the awardee and the National Cancer Institute (NCI). The following Terms of Cooperation include the Programmatic Responsibilities of the Awardees, the Nature of Assistance by NCI Staff, Collaborative Responsibilities, and Arbitration Procedures (Attachment 1).

These special Terms and Conditions of Award are in addition to and not in lieu of otherwise applicable OMB administrative guidelines, Federal Regulations, including HHS Grant Administration Regulations at 42 CFR Part 52, 45 CFR Parts 74 and 92, and other HHS, PHS, and NIH Grant Administration policy statements.

The following administrative terms also apply:

NEW REQUIREMENT BEGINNING NOVEMBER 1, 2001: If a competing continuation application is submitted for this project, the requested budget is subject to the direct cost cap calculated in accordance with the National Cancer Institute's (NCI) policy, "Policy for Allowable Requested Budget Levels of Competing Continuation (Type 2) R01 and U01 Applications." This policy was announced in the NIH Guide for Grants and Contracts on August 7, 2001 and is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-CA-01-016.html>.

For most awards, the last noncompeting year has the largest budget; and the competing continuation budget request cannot exceed an increase of 20% over the direct cost level of the last noncompeting year. However, in order to determine the maximum amount that you can request, it is recommended that you also read Frequently Asked Questions, which are posted on the NCI Internet at <http://deainfo.nci.nih.gov/grantspolicies/newbudgetcap-faq.htm>. It is extremely important for you to read and adhere to these guidelines. Competing continuation applications requesting increases in excess of this policy without prior approval from the NCI may be returned without review and may result in the loss of a full review cycle.

A request for a hard copy of the policy and/or questions about the policy should be directed to the NCI grants management specialist or the NCI program director identified on the award notice.

INFORMATION This revised award reflects NCI approval of the change of principal investigator from Dr. Rice to Dr. Vincent James Coglianò, as requested in the grantee's letter dated 4/22/03.

INFORMATION This award utilizes as an offset the unobligated balance from the 20-year financial status report.

INFORMATION Your request for additional funds has not been approved. National Cancer Institute staff have determined that there is sufficient flexibility within the awarded grant budget to permit the research to proceed.

INFORMATION For administrative and management concerns, contact the Grants Management Specialist, Joy Kearse, at (301) 846-1010, [kearsej@mail.nih.gov](mailto:kearsej@mail.nih.gov). For programmatic and scientific concerns, contact the Program Director, Dr. Davis Longfellow, at (301) 496-5471.

INFORMATION In a continuing effort to provide exceptional customer service, the NCI Grants Administration Branch has set up a Feedback address on its web site (<http://www.nci.nih.gov/admin/gab/index.htm>). General concerns and issues related to NCI grants policies, procedures, and practices can be sent to the Customer Liaison using this feature. Specific questions or concerns related to this grant should be addressed to the Grants Management Specialist listed in the Terms of Award.

DAVID G. LONGFELLOW, Program Official  
Phone: 301-496-5471 Email: [dl58s@nih.gov](mailto:dl58s@nih.gov) Fax: 301-496-1040

Joy Kearse, Grants Specialist  
Phone: 301-846-1010 Email: [kearsej@mail.nih.gov](mailto:kearsej@mail.nih.gov)

## SPREADSHEET

GRANT NUMBER: 5 U01 CA033193-22

P.I.: Cogliano, Vincent James

INSTITUTION: WORLD HLTH ORG INTL AGCY RES ON CANCER

	YEAR 22	YEAR 23
	=====	=====
Salaries and Wages	317,259	(b)(5)
Fringe Benefits	105,872	
Personnel Costs	423,131	
Consultant Services	37,461	
Travel Costs	3,122	
Other Costs	151,628	
TOTAL FEDERAL DC	615,342	
TOTAL FEDERAL F&A	79,994	
TOTAL COST	695,336	

	YEAR 22	YEAR 23
	=====	=====
A Cost Rate 1	13.00%	(b)(5)
F&A Cost Base 1	615,342	
F&A Costs 1	79,994	

Collaborative Terms of Award

Nature of Collaboration with NCI Staff

NCI has certain responsibilities in terms of this cooperative agreement which involve assistance, information support, and scientific collaboration.

1. Scientific Resource

Since the monographs on each chemical which appear in the volumes published by IARC are fundamentally an international information resource and data bank on carcinogenesis and evaluation of qualitative risk of chemicals to humans, NCI, in an assistance and cooperative role, provides information and data which assist IARC staff in the preparation of certain sections of the final monograph (Sections 1.1 to 2.3). Sections 3.1 to 4.3 are developed by the Working Groups which consist of international scientists who review all these documents at the time of the meetings (3 per year) in Lyon, France. The National Cancer Institute, through arrangements with a contractor will provide such assistance.

2. Planning for Meetings of the Working Group

The IARC project is one of international support with NCI being the USA supporter for the monograph and the Information Bulletins on the Survey of Chemicals Being Tested for Carcinogenicity. This bulletin is a listing of chemicals being tested in laboratories throughout the world. Under the Cooperative Agreement, NCI:

- a. Makes suggestions to IARC on types of chemicals that should be evaluated at the three planned working group meetings per year held in Lyon, France.
- b. Makes suggestions and gives assistance to IARC as to USA resource people who should attend and participate in Working Group meetings. Personnel from regulatory agencies and trade associations should attend as observers.

3. Program Involvement in Relation to Input from NCI

Under the section on scientific resources, reference was made to NCI input as to data on production, occurrence, analysis, and use of chemicals. NCI, also provides information relevant to carcinogenicity on chemicals tested in U.S. laboratories. These data are then incorporated in the Information Bulletin on the Survey of Chemicals Being Tested for Carcinogenicity.

## 5. IARC 33193

### Collaborative Terms of Award

In discussing certain phases of work that involve assistance and collaboration on the part of the NCI with IARC, reference was made to the essentiality of effective liaison and support. Participation by the NCI Program Director in the working group meetings in Lyon, France could be either as an observer or as a representative of NCI or as a full member of the working group in his personal capacity as a scientist.

#### 4. Reporting Requirements

NCI wishes to continue a semi-annual reporting requirement with scheduling or due dates for reports worked out by mutual arrangement between NCI staff and the IARC principal investigator. The volumes of monographs, supplements and survey bulletins are actually exhibits of achievements and accomplishments. Consequently, the semi-annual reports should dwell on planning, participation, selection of chemicals, problems of interfacing and cooperation and logistical matters. In addition, an annual report to be included in the required continuation applications should reflect that the project continues to conform to the purposes, objectives, and conditions of the award and has substantial programmatic involvement by NCI with the performer of the project.

#### 5. Publication and Distribution

One of the significant features of the IARC project in development of this international, authoritative reference source is the publication and distribution, on a world-wide basis, of these volumes, including the supplements to the volumes listing Chemicals and Industrial Processes Associated with Cancer in Humans, as well as the Survey Bulletins.

The National Cancer Institute will receive approximately 400 copies of each volume published. The NCI distributes these copies to NCI staff, representatives of other agencies interested in environmental and occupational carcinogenesis, selected university scientists engaged in carcinogenesis research, public health organizations and medical libraries. Therefore, many organizations and scientists in the USA and abroad benefit from this program, which is partially supported by the National Cancer Institute.

Department of Health and Human Services  
Public Health Services**Grant Progress Report**  
**JUN 27 2003**Review Group Type Activity Grant Number  
S U01 CA33193-22Total Project Period  
From: 09/01/1985 Through: 08/31/2005Requested Budget Period:  
From: 09/01/2003 Through: 08/31/2004

## 1. TITLE OF PROJECT

Evaluation of Carcinogenic Risks to Humans

## 2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR

(Name and address, street, city, state, zip code)

Vincent James COGLIANO  
Carcinogen Identification & Evaluation  
International Agency for Research on Cancer  
150 cours Albert Thomas  
69372 Lyon Cedex 08, France

## 3. APPLICANT ORGANIZATION

(Name and address, street, city, state, zip code)

International Agency for Research on Cancer  
150 cours Albert Thomas  
69372 Lyon Cedex 08  
France

## 2b. E-MAIL ADDRESS

cogliano@iarc.fr

## 4. ENTITY IDENTIFICATION NUMBER

1900210016A1

## 2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT

Carcinogen Identification &amp; Evaluation

## 5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL

Director, Division of Administration & Finance  
International Agency for Research on Cancer  
69372 Lyon Cedex 08, France

## 2d. MAJOR SUBDIVISION

E-MAIL: hay@iarc.fr

## 6. HUMAN SUBJECTS

☒ No  
☐ Yes6a. Research Exempt  
☐ No ☐ Yes

6b. Human Subjects Assurance No.

If Exempt ("Yes" in 6a):  
Exemption No.6c. NIH-Defined Phase III  
Clinical Trial ☐ No ☐ YesIf Not Exempt ("No" in 6a):  
IRB approval date☐ Full IRB or  
☐ Expedited Review

## 7. VERTEBRATE ANIMALS

☒ No  
☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

## 8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT \$689,900

8b. TOTAL \$779,587

## 9. INVENTIONS AND PATENTS

☒ No ☐ Yes If "Yes," ☐ Previously Reported  
☐ Not Previously Reported

## 10. PERFORMANCE SITE(S) (Organizations and addresses)

International Agency for Research on Cancer  
150 cours Albert Thomas  
69372 Lyon Cedex 08  
France11a. PRINCIPAL INVESTIGATOR  
OR PROGRAM DIRECTOR (Item 2a)

Vincent James Coglian

TEL +33 472 73 84 76

FAX +33 472 73 83 19

11b. ADMINISTRATIVE OFFICIAL  
NAME (Item 5)

Valerie Hay

TEL +33 472 73 84 67

FAX +33 472 73 85 75

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT  
ORGANIZATION (Item 14)

NAME Paul Kleihues

TITLE Director

TEL +33 472 73 86 84

FAX +33 472 73 85 75

E-MAIL kleihues@iarc.fr

## 12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application

SIGNATURE OF P/MPD NAMED IN 2a.  
(In ink. "Per" signature not acceptable.)

Vincent James Coglian

DATE

23 June 2003

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN  
11c. (In ink. "Per" signature not acceptable.)

Paul Kleihues

DATE

25 June 03

22-year recommended level

21-year requested budget

Principal Investigator/Program Director (Last, first, middle): COGLIANO, Vincent James

DETAILED BUDGET FOR NEXT BUDGET PERIOD - DIRECT COSTS ONLY		FROM 09/01/03	THROUGH 08/31/04	GRANT NUMBER CA 33193-22	
PERSONNEL (Applicant organization only)		TYPE APPT. (months)	% EFFORT ON PROJ.	DOLLAR AMOUNT REQUESTED (omit cents)	
NAME	ROLE ON PROJECT			SALARY REQUESTED	FRINGE BENEFITS
COGLIANO, V. J.	Replaced Dr. Rice Principal Investigator	(b)(4), (b)(6)	(b)(4), (b)(6)	-0	-0
BAAN, R. ✓	Scientist			88,600	29,500
STRAIF, K. ✓	Scientist			90,900	30,300
SECRETAN, B. ✓	Scientist			58,500	19,600
EL-GHISSASSI, F.*	Scientist			29,300	9,800
LEZERE, M. ✓	Publication support			51,300	17,100
EGRAZ, S. ✓	Archivist			37,100	12,400
*Partly funded from other sources. See also list on page 3 for additional project staff not funded by NCI grant.					
(382,900) FTE 2002: 7.5 FTE 2003: 6.7 SUBTOTALS				355,700	118,700
CONSULTANT COSTS				(30,176)	(139,541)
(50,000) See page 3					42,000
EQUIPMENT (Itemize)					(54,636)
SUPPLIES (Itemize by category)					
TRAVEL (3,500) One trip of the PI to USA for a scientific meeting & to consult with NCI program officials					(4,262) 3,500
PATIENT CARE COSTS		INPATIENT			
		OUTPATIENT			
ALTERATIONS AND RENOVATIONS (Itemize by category)					
OTHER EXPENSES (Itemize by category) See page 3 (161,018)					(160,631) 170,000
SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD				723,970	\$689,900
CONSORTIUM/CONTRACTUAL COSTS		DIRECT COSTS			
		FACILITIES AND ADMINISTRATIVE COSTS			
TOTAL DIRECT COSTS FOR NEXT PROJECT PERIOD (Item 9a, Face Page) (597,418)				723,970	\$689,900

**BUDGET JUSTIFICATION**

GRANT NUMBER

CA 33193-22

Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended. Use continuation pages if necessary.

**PERSONNEL**

Grosse, Y.	Scientist	(b) months	(b)(4), effort	No salary support from NCI
Mitchell, J.	Publication support	(4), months	(b)(6) effort	No salary support from NCI
Perez, E.	Secretary	(b)(6) months	effort	No salary support from NCI

Scientists from other units of IARC (see appendices to Progress Report Summary for list)

**CONSULTANT COSTS**

- Preparation of draft monographs	
\$400/expert x 20 experts x 2 Monographs =	\$ 16,000
- Editing of Monographs	
\$13,000 per volume x 2 volumes	\$ 26,000
	<u>\$ 42,000</u>

**OTHER EXPENSES**

- Working groups (travel and per diem) (\$45,000 x 2)	\$ 90,000
- Printing of Monographs (\$25,000 x 2)	\$ 50,000
- Distribution of free monographs (\$6,000 x 2)	\$ 12,000
- Reprint requests	\$ 8,000
Books, journals & reproduction costs	<u>\$ 10,000</u>
	<b>\$170,000</b>

**CURRENT BUDGET PERIOD**FROM  
09/01/02THROUGH  
08/31/03Total estimated  
expenditureEstimated  
unobligated balance

DIRECT COSTS	\$ 597,418	\$ 0
INDIRECT COSTS	\$ 77,664	\$ 0
TOTAL	\$ 675,082	\$ 0

**Budget Justification**

The funds requested from the National Cancer Institute for the continuation of the currently supported project amount to \$689,900, indirect costs excluded, for the period 1 September 2003 to 31 August 2004. The Committed Level for this period in the Notice of Grant Award dated 30/08/02 amounts to \$615,342, after the 15% reduction applied on the Corrected Recommended Level of Support.

The budget essentially represents the cost of maintaining the ongoing programme, i.e. three meetings and three Monographs volumes per year, assuming that one working group and one volume will be financed from other sources. The number of posts to be supported by the grant is the same as in Year 21: 3.5 scientists and 2 secretarial staff.

The increase of \$92,482 above the approved budget for Year 21 relates to the following factors:

Approved budget for Year 21		\$597,418
<b>PLUS: Currency realignements</b>	<b>\$87,752 (14.69%)</b>	
<b>Cost increase</b>	<b><u>\$ 4,730 ( 0.79%)</u></b>	
		<b><u>\$ 92,482</u></b>
<b>REQUESTED BUDGET FOR YEAR 22</b>		<b>\$689,900</b>

The budget for Year 21 was developed and approved with an exchange rate of €1.065 to the US dollar, compared with the rate of €0.849 used for the present application. This drop of the dollar value results in an increase of 25% of the dollar equivalent of Euro expenditure.

The cost increase (\$28,873) resulting mainly from increased staff entitlements is offset by a decrease of \$24,143 in other budget categories.

**BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel in the order listed for Form Page 2.  
Follow the sample format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME		POSITION TITLE	
COGLIANO, VINCENT JAMES		Chief, Carcinogen Identification and Evaluation	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Catholic University, Washington DC	A.B.	1973	Mathematics
University of Michigan, Ann Arbor MI	M.A.	1975	Mathematics
Cornell University, Ithaca NY	Ph.D.	1982	Operations Research

**A. Positions and Honors****Employment**

1975-1978 Mathematician, Defense Communications Agency, Washington DC.  
 1978, 1979 Regulatory Policy Analyst, U.S. Environmental Protection Agency, Washington DC.  
 1981-1983 Manufacturing Engineer, IBM Corporation, Endicott NY.  
 1983-1985 Statistician, Office of Policy, Planning and Evaluation, U.S. EPA, Washington DC.  
 1985-1990 Statistician, Carcinogen Assessment Group, U.S. EPA, Washington DC.  
 1990-1995 Chief, Carcinogen Assessment Statistics & Epidemiology Branch, EPA, Washington.  
 1995-2001 Chief, Quantitative Risk Methods Group, U.S. EPA, Washington DC.  
 2000-2001 Acting Director Washington Div'n, National Center for Environmental Assessment, EPA.  
 2001-2003 Special Assignment: Chair of Cancer Guideline Writing Group, U.S. EPA, Washington.  
 2003-present Chief, Carcinogen Identification and Evaluation,  
 International Agency for Research on Cancer, Lyon France.

**Fellowships and Assistantships**

1969-1973 Merit Scholarship, Catholic University.  
 1973-1975 Teaching Fellowship, University of Michigan.  
 1978-1981 Research Assistantship, Cornell University.

**Honors**

1973 *Phi Beta Kappa*.  
 1984 EPA *Silver Medal* for support of national decision on ethylene dibromide in food supply.  
 1993 Scientific Achievement Award for publication on early-life sensitivity to vinyl chloride.  
 1996 EPA *Bronze Medal* for developing consensus information on chemical carcinogen risks.  
 1998 EPA *Bronze Medal* for managing international risk assessment training program.  
 1998 Scientific Achievement Award for publication on cancer risks from environmental PCBs.  
 1998 EPA *Gold Medal* for innovative assessment of PCB health hazards.  
 1999 EPA *Peer Award* for international environmental protection.  
 2000 EPA *Peer Award* for teamwork.  
 2001 Scientific Achievement Award for monograph on trichloroethylene health risks.  
 2001 Scientific Achievement Award for publication on health implications of air toxics levels.  
 2002 EPA Tribute of Appreciation for technical support at the Hudson River PCB site.  
 2002 EPA *Silver Medal* for guidance on health risk assessment of chemical mixtures.  
 2002 EPA award for outstanding technical assistance to the regions or program offices

## **B. Selected Peer-Reviewed Publications**

### Scientific journal articles

- Schruben L, Coglian VJ (1987). An experimental procedure for simulation response surface model identification. *Communications of the ACM* 30(8): 716-730.
- Cogliano VJ, Farland WH, Preuss PW, Wiltse JA, Rhomberg LR, Chen CW, Mass MJ, Nesnow S, White PD, Parker JC, Wuerthele SM (1991). Carcinogens and human health: part 3. *Science* 251(4994): 606-607 (letter)
- Cogliano VJ, Parker JC (1992). Some implications of toxicology and pharmacokinetics for exposure assessment. *Journal of Exposure Analysis and Environmental Epidemiology*, Suppl 1: 189-207.
- Vater ST, Velazquez SF, Coglian VJ (1995). A case study of cancer data set combinations for PCBs. *Regulatory Toxicology and Pharmacology* 22: 2-10.
- Velazquez SF, Schoeny R, Rice GE, Coglian VJ (1996). Cancer risk assessment: historical perspectives, current issues, and future directions. *Drug and Chemical Toxicology* 19(3): 161-185.
- Cogliano VJ, Hiatt GFS, Den A (1996). Quantitative cancer risk assessment for vinyl chloride: indications of early-life sensitivity. *Toxicology* 111: 21-28.
- Maul EA, Coglian VJ, Siegel Scott C, Barton HA, Fisher JW, Greenberg M, Rhomberg L, Sorgen SP (1997). Trichloroethylene health risk assessment: a new and improved process. *Drug and Chemical Toxicology* 20(4): 427-442.
- Cogliano VJ (1997). Plausible upper bounds: are their sums plausible? *Risk Analysis* 17(1): 77-84.
- Cogliano VJ (1998). Assessing the cancer risk from environmental PCBs. *Environmental Health Perspectives* 106(6): 317-323.
- Brouwer A, Longnecker MP, Birnbaum LS, Coglian J, Kostyniak P, Moore J, Schantz S, Winneke G (1999). Characterization of potential endocrine-related health effects at low-dose levels of exposure to PCBs. *Environmental Health Perspectives* 107(suppl 4): 639-650.
- Scott CS, Coglian VJ, eds (2000). Trichloroethylene health risks—state of the science. *Environmental Health Perspectives* 108(suppl 2).
- Woodruff TJ, Caldwell J, Coglian VJ, Axelrad DA (2000). Estimating cancer risk from outdoor concentrations of hazardous air pollutants in 1990. *Environmental Research Section A* 82: 194-206.
- Cogliano VJ, Scott CS, Caldwell JC, Farland WH (2001). Trichloroethylene: using new information to improve the cancer characterization. *Human and Ecological Risk Assessment* 7(4): 755-766.

### Authorship or Co-Authorship of Major EPA Scientific Publications

- Methodology for evaluating potential carcinogens in support of reportable quantities under CERCLA section 102, EPA/600/8-89/053, June 1988.
- Evaluation of the Potential Carcinogenicity of Lead and Lead Compounds, external review draft, EPA/600/8-89/045A, March 1989. Peer-reviewed by EPA's Science Advisory Board and Clean Air Scientific Advisory Committee in public meetings.
- Evaluation of the potential carcinogenicity of [name of compound], EPA/600/8-91/nnn, August 1991 [series of 191 carcinogen profiles]. Peer-reviewed by independent scientists.
- PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures, EPA/600/P-96/001F, [cfpub.epa.gov/ncea/cfm/recorddisplay.cfm?deid=12486](http://cfpub.epa.gov/ncea/cfm/recorddisplay.cfm?deid=12486), September 1996. Peer-reviewed by a panel of independent scientists in a public meeting.

Principal Investigator/Program Director (Last, first, middle): COGLIANO, Vincent James

Toxicological Review of Vinyl Chloride, EPA/635R-00/004, [www.epa.gov/iris/subst/1001.htm](http://www.epa.gov/iris/subst/1001.htm), May 2000. Peer-reviewed by a panel of independent scientists.

Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures, EPA/630/R-00/002, [cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=20533](http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=20533), August 2000. Peer-reviewed by EPA's Science Advisory Board in a public meeting.

Trichloroethylene Health Risk Assessment, external review draft, EPA/600/P-01/002A, [cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=23249](http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=23249), August 2001. Peer-reviewed by EPA's Science Advisory Board in a public meeting.

Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens, external review draft, EPA/630/R-03/003, [cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=55446](http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=55446), February 2003. Peer-reviewed by EPA's Science Advisory Board in a public meeting.

Guidelines for Carcinogen Risk Assessment, draft final, NCEA-F-0644A, [cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=55445](http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=55445), March 2003. Peer-reviewed by EPA's Science Advisory Board in public meetings in 1997 and 1999.

### Books and Book Chapters

Preuss PW, Coglian VJ, White PD (1989). The perils of prudence. In: Mohr U, Bates DV, Dungworth DL, Lee PN, McClellan RO, Roe FJC, eds, *Assessment of Inhalation Hazards: Integration and Extrapolation Using Diverse Data*. Berlin: Springer-Verlag, 337-347.

Hiatt GFS, Coglian VJ, Becker RA, Siegel DM, Den AR (1993). Vinyl chloride action levels: indoor air exposures at a Superfund site. In: U.S. DHHS, ed, *Hazardous Waste and Public Health: International Congress on the Health Effects of Hazardous Waste*. Princeton: Princeton Scientific Publishing.

Velazquez SF, Schoeny R, Coglian VJ, Rice GE (1996). Cancer risk assessment: historical perspectives, current issues, and future directions. In: Fan AM, Chang LW, eds, *Toxicology and Risk Assessment: Principles, Methods, and Applications*. New York: Marcel Dekker, 219-243.

Coglian VJ, Luebeck EG, Zapponi GA, eds (1999). *Perspectives on biologically based cancer risk assessment*. New York: Kluwer Academic/Plenum Publishers.

Coglian VJ (2001). Considerations for setting reference values for environmental PCBs. In: Roberston LW, Hansen LG, eds, *PCBs: Recent Advances in the Environmental Toxicology and Health Effects*. Lexington: University of Kentucky Press.

Coglian VJ, Caldwell JC, Scott CS (2001). Risk assessment and risk management in the European Community and in the United States. In: Chyczewski L, Niklinski J, Pluygers E, eds, *Endocrine Disrupters and Carcinogenic Risk Assessment*. Amsterdam: IOS Press.

Coglian VJ, Caldwell JC, Scott CS (2001). The use of modeling in risk assessment. In: Chyczewski L, Niklinski J, Pluygers E, eds, *Endocrine Disrupters and Carcinogenic Risk Assessment*. Amsterdam: IOS Press.

### **C. Ongoing Research Support**

European Commission  
US Environmental Protection Agency  
US National Institute of Environmental Health Sciences

**See page 13 (Other active support) for grant titles and grant numbers**

**BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel in the order listed for Form Page 2.  
Follow the sample format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME		POSITION TITLE	
Marie Beatrice Secretan		Scientist	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
University of Geneva, Switzerland	Licence (BSc)	1985-1989	Biochemistry
University of Geneva, Switzerland	Diplome (MSc)	1989-1991	Biochemistry
St. Bartholomew and the Royal London School of Medicine and Dentistry, London, UK	PhD	1992-1996	Toxicology
Ibidem	Post-doc	1996-1997	Chemical carcinogenesis
Harvard School of Public Health, Boston, MA	Post-doc	1998-2001	Cancer cell biology
UCLA School of Public Health, Los Angeles, CA	Post-doc	04-06 2001	Cancer cell biology
IARC/WHO, Lyon, France	Post-doc	2001-2002	Gene-environment interactions

**Work experience**

Sept. 2002 - present: Unit of Carcinogen Identification and Evaluation, IARC/WHO, Lyon, France  
Responsible for the checking of manuscripts for the publication of "IARC monographs on the evaluation of carcinogenic risks to humans", published by IARC. Current monographs are:

- Active tobacco smoking: An update
- Passive tobacco smoking
- Some drinking-water disinfectants and contaminants, including arsenic
- Chemopreventive effects of fruits and vegetables (for the Unit of Chemoprevention)
- Betel-quid and areca nut chewing

Sept. 2001 - Aug. 2002: Unit of Gene-Environment Interactions, IARC/WHO, Lyon, France (laboratory of Dr. E. van Dyck)

- Biological characterisation of RDM-1, a novel Rad52 homologue

Jan. 1998 - June 2001: Dept. of Cancer Cell Biology, Harvard School of Public Health, Boston, MA (Jan. 1998 - Feb. 2001) and Dept. of Environmental Health, UCLA School of Medicine and Public Health, Los Angeles, CA (March-June 2001): laboratory of RH Schiestl

- Double strand break repair by recombination in DNA repair deficient CHO cell lines
- P53 involvement in X-ray induced intrachromosomal recombination in mice
- Delayed re-induction of p53 and oxidative stress in irradiated human diploid fibroblasts

Oct. 1992 - Oct. 1997: Dept. of Toxicology, St. Bartholomew & the Royal London School of Medicine and Dentistry, London, UK, under the supervision of Dr. CJ Powell

- Relationship between toxicity, mitogenicity and carcinogenicity in the rat liver

Oct. 1991 - Sept. 1992: GlaxoWellcome, Biomedical Research Institute, Geneva, Switzerland, under the supervision of Dr. J. Whelan

- Activation by NFkB of the ELAM-1 promoter sequence in *S. Pombe*

Oct. 1990 - July 1991: ISREC, Dept. of Chemical Carcinogenesis, Epalinges s/ Lausanne, Switzerland, under the supervision of Dr RM Tyrrell

- Determination of DNase I hypersensitive sites in the human heme oxygenase gene

### Work experience in scientific writing

Reports: compilation, summarisation and critical evaluation of toxicology reports for the European Union review on food contact chemicals (indirect food additives).

Translations: Biomedical translations of questionnaires used for surveys in hospitals and other medical institutions from French into English and vice-versa, and German into English.

### Languages and computer literacy

Languages: French (mother tongue), English (excellent), German (excellent), Italian (good), Spanish (basic knowledge)

Computer literacy: Word, Excel, Power Point, Harvard Graphics, Harvard ChartXL, Cricket Graph, Gene Construction Kit, EndNote

### Fellowships and bursaries

Jan. 1999 – Dec. 1999: Post-doctoral fellowship awarded by the Swiss Cancer League.

Jan. 1998 – Dec. 1998: Post-doctoral fellowship awarded by the Swiss National Fund.

Oct. 1992 - April 1996: PhD studentship awarded by *GlaxoWellcome*, R & D, Ware, UK.

March 1994 and 1996: Student bursary awarded by the British Toxicology Society for the participation at international scientific meetings.

### Publications

Rugo RE, **Secretan MB** and Schiestl RH (2002) X-radiation causes a persistent induction of reactive oxygen species and a delayed reinduction of TP53 in normal human diploid fibroblasts. *Radiation Research*, **158** (2), 210-9.

Aubrecht J, **Secretan MB**, Bishop AJ and Schiestl RH (1999) Involvement of p53 in X-ray induced intrachromosomal recombination in mice. *Carcinogenesis*, **20** (12), 2229-36.

**Secretan MB**, Cottrell S and Powell CJ (1997) Progression of precarcinogenic effects in methapyrilene-treated rats. *Human Exp. Toxicol.* **16** (1), 53.

Freathy C, Cottrell S, **Secretan MB** and Powell CJ (1997) Young rats are more susceptible than old rats to the relative induction of preneoplastic lesions after a 13 week exposure to a non-genotoxic carcinogenic drug. *Human Exp. Toxicol.* **16** (1), 46.

Powell CJ and **Secretan MB** (1995) Induction and reversibility of genotoxic and non-genotoxic carcinogen-induced altered hepatocyte foci in rats. *Toxicol. Pathol.* **23** (6), 757-758.

Cottrell S, **Secretan MB** and Powell CJ (1995) Chronic methapyrilene administration increases cell proliferation in diploid hepatocytes with a concomitant decrease in polyploidisation. *Human Exp. Toxicol.* **14**, 770.


**Secretan MB** and Powell CJ (1995) Reversibility of the toxic and precarcinogenic effects of methapyrilene in rats. *Human Exp. Toxicol.* **14**, 769.

**Secretan MB** and Powell CJ (1994) Early toxic and carcinogenic effects of methapyrilene in rat liver. *Toxicol. Lett.* **74** (suppl. 1), 77.

Powell CJ, **Secretan MB** and Cottrell S (1994) Preneoplastic changes during non-genotoxic hepatocarcinogenesis. In: Skouteris, G.G. (Ed.) *Liver carcinogenesis, NATO ASI Series, Vol. H88*, pp. 215-229. Berlin - Heidelberg: Springer-Verlag.

**Manuscripts in preparation**

(b)(4), (b)(6)



**Secretan MB**, Cottrell S and Powell CJ. The early effects of a non-genotoxic carcinogen on cell proliferation and altered hepatocyte foci are only partly reversible.

**Secretan MB**, Cottrell S and Powell CJ. Inhibitory effects of paracetamol (acetaminophen) on the induction of altered hepatocyte foci in Han-Wistar rats.

**BIOGRAPHICAL SKETCH**

Provide the following information for the key personnel in the order listed for Form Page 2.  
Follow the sample format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME		POSITION TITLE	
EL GHISSASSI Fatiha		Scientist	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Scientific and Medical University of Grenoble, France	B Sc	1980	Structural and Metabolic Biochemistry and Degree in Organic Chemistry
University Claude Bernard, Lyon I	Master of Science	1982	Molecular Biology and Physicochemistry; Endocrine Biochemistry
University Claude Bernard, Lyon I	DEA	1983	Biochemistry Option Pharmacology
University Claude Bernard, Lyon I	Doctorate in Sciences	1986	Biochemistry
University Claude Bernard, Lyon I, France	PhD	1995	Biochemistry (Toxicology)

**Positions**

- Aug 02 to present     Scientist, Carcinogen Identification & Evaluation, IARC, Lyon (Supervisor Dr R. Baan). Reviewed and ensured the scientific accuracy of IARC monograph, summaries of studies on absorption, distribution, metabolism and excretion; toxic effects; reproductive and developmental effects; and genetic and related effects (section 4 of each monograph). This was done for the monographs on "tobacco smoke" (vol 83) and "some drinking-water disinfectants and contaminants, including arsenic" (vol 84) Participated as co-rapporteur in section 4 in the IARC monograph meeting on "Betel Quid and areca-nut chewing and some related nitrosamines" (vol 85)
- Feb 02-July 02     Visiting Scientist in Molecular Carcinogenesis Group (Chief: Dr P. Hainaut), IARC, Lyon 'Induction of p53 protein activity by the aminothiol WR2721 (amifostine): a possible involvement of polyamine moiety in the mechanism of cytoprotection'
- 1997-2001     Post-doctoral fellowship in Léon Bérard Center, Fundamental and Applied Oncology Department, INSERM U453, Lyon "Study of biologic function of p53 target gene, BTG2 : effect of its expression on neuronal proliferation, differentiation and apoptosis of PC12 cells" Supervisor Pr A. Puisieux. Post-doctoral fellowship awarded by the Regional Center of Research on Cancer 'Léon Bérard'
- 1996-1997     Post-doctoral fellowship in Unit of Mechanisms of Carcinogenesis (MCA), IARC, Chief Dr R. Montesano "Modulation of DNA-Binding activity of the tumour suppressor protein p53 by an antioxidant Amifostine: mechanism of cytoprotection" Supervisor Dr P. Hainaut Post-doctoral fellowship awarded by IARC and USB Pharma
- 1991-1996     Ph.D Thesis in Unit of Environmental Carcinogens and Host Factors, (ECH), IARC, Chief Pr H. Bartsch "Study of metabolic factors which could modulate the formation of ethenoadducts, potential biomarkers of carcinogenesis by vinyl chloride and by lipid peroxidation " Supervisor Dr A. Barbin Student fellowship awarded by IARC, INSERM and Elf-Atochem

- 1987-1991 Technician in Unit of Environmental Carcinogens and Host Factors, IARC "Comparison of effects of diet and gut bacteria on microcapsule trapping and benzo(a)pyrene metabolism" Supervisor Dr I. O'Neill. "N-nitrosamine metabolites analysis by Gas Chromatography-Thermal-Energy-Analyser (GC-T.E.A)" Supervisor Dr H. Ohshima
- 1982-1987 Studentship in Doctoral Biochemistry third cycle. Laboratory of Endocrine biochemistry, in Sainte-Eugénie Hospital, Lyon Sud. "Analysis of bile acids and cholesterol by gas chromatography in meconium of normal newborn and new-born affected by cystic fibrosis" Supervisor Pr A. Revol, Director Pr D. Gautheron

## PUBLICATIONS

- El Ghissassi F., Valsesia-Wittmann S., Falette N., Duriez C., Walden P.D. & Puisieux A. (2002) BTG2(TIS21/PC3) induces neuronal differentiation and prevents apoptosis of terminally differentiated PC12 cells. *Oncogene*, **21**, 6772-6778
- North S., Pluquet O., Maurici D., El Ghissassi F. & Hainaut P. (2002) Restoration of wild-type conformation and activity of a temperature-sensitive mutant of p53 (p53<sup>v272M</sup>) by the cytoprotective aminothiols WR1065 in the esophageal cancer cell line TE-1. *Mol Carcinog*, **33**, 181-188
- North S., El Ghissassi F., Pluquet O., Verhaegh G. & Hainaut P. (2000) The cytoprotective aminothiols WR1065 activates p21waf-1 and down regulates cell cycle progression through a p53-dependent pathway. *Oncogene*, **19**, 1206-14  
North S. and El Ghissassi F. contributed equally to this paper
- Cortes U., Moyret-Lalle C., Falette N., Duriez C., Ghissassi E.F., Barnas C., Morel A.P., Hainaut P., Magaud J-P. & Puisieux A. (2000) BTG gene expression in the p53-dependent and independent cellular response to DNA damage. *Mol Carcinog*, **27**, 57-64
- El Ghissassi F., Barbin A. & Bartsch H. (1998) Metabolic activation of vinyl chloride by rat liver microsomes: low-dose kinetics and involvement of cytochrome P450 2E1. *Biochem Pharmacol*, **55**, 1445-1452
- Guichard Y., El Ghissassi F., Nair J., Bartsch H. & Barbin A. (1996) Formation and accumulation of DNA ethenobases in adult Sprague-Dawley rats exposed to vinyl chloride. *Carcinogenesis*, **17**, 1553-1559
- El Ghissassi F., Barbin A., Nair J. & Bartsch H. (1995) Formation of 1,N<sup>6</sup>-ethenoadenine and 3,N<sup>4</sup>-ethenocytosine by lipid peroxidation products and nucleic acids bases. *Chem. Res. Toxicol*, **8**, 278-283
- El Ghissassi F., Boivin S., LeFrançois L., Barbin A. & Marion M.J. (1995) Glutathione transferase Mu1-1 (GSTM1) genotype in individuals exposed to vinyl chloride in relation to "vinyl chloride disease" and liver angiosarcoma. *Clinical chemistry (Suppl)*, **41**, 1922-1924
- Sierra R., Ohshima H., Munoz N., Teuchmann S., Pena A-S., Malaveille C., Pignatelli B., Chinnock A., El Ghissassi F. & Chen C. (1991) Exposure to N-nitrosamines and other risk factors for gastric cancer in Costa Rican children. *IARC-Sci-Publ.*, **105**, 162-167
- O'Neill I.K., Goldberg M., El Ghissassi F. & Rojas-Moreno M. (1991) Dietary fibre, fat and beef modulation of colonic nuclear aberrations and microcapsule trapped G.I metabolites of Benzo(a)pyrene treated C57-B6 mice consuming human diets. *Carcinogenesis*, **12**, 175-180

Principal Investigator/Program Director (Last, first, middle): Cogliano, Vincent James

**Other Active Support - Dr V. J. Coglian, Principal Investigator**

(b) (4)

1/01/03 – 31/12/03  
\$52,100

(b) (4) %

The IARC Monographs 2003

No overlap with the NCI cooperative agreement. Funds used to support the 3<sup>rd</sup> Monographs meeting each year and scientific or advisory meetings relevant to the Monographs Programme.

**R-82928801-1**

1/06/03 – 31/05/03  
\$22,100

(b) (4) %

US Environmental Protection Agency

International Research, Evaluation and Education in Environmental Carcinogenesis

No overlap with the NCI cooperative agreement. Funds used to support the 3<sup>rd</sup> Monographs meeting each year and scientific and advisory meetings relevant to the Monographs Programme.

**US National Institute of Environmental Health Sciences**

(no time limit)

\$79,600 in 2003

(b) (4) %

Donation in support of the Monographs Programme, used to support the 3<sup>rd</sup> Monographs meeting each year and scientific and advisory meetings relevant to the Monographs Programme.

(Other key personnel have no active support)

**PROGRESS REPORT SUMMARY**

GRANT NUMBER

CA33193-21

PERIOD COVERED BY THIS REPORT

PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR  
Cogliano, Vincent JamesFROM  
09/01/2002THROUGH  
08/31/2003

APPLICANT ORGANIZATION

International Agency for Research on Cancer

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)

Evaluation of Carcinogenic Risks to Humans

A. Human Subjects (Complete Item 6 on the Face Page)

Involvement of Human Subjects



No Change Since Previous Submission



Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)

Use of Vertebrate Animals



No Change Since Previous Submission



Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

**Has there been a change in the other support of key personnel since the last reporting period?**

The present active grants, which continue the level of support from previous years, are listed on page 13.

**Will there be, in the next budget period, a significant change in the level of effort for key personnel from what was approved for this project?**

See attached table, page 17.

**Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total budget?**

No.

**REPORT ON RESEARCH PROGRESS**

**a. Specific aims** of the *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans* are to critically review and evaluate the strength of the total published scientific evidence for carcinogenic risk from biological, physical, and chemical agents, complex mixtures, and environmental circumstances to which humans are exposed. Agents and exposures are classified by levels of evidence for human carcinogenicity, which range from *carcinogenic to humans* (Group 1) to *probably not carcinogenic to humans* (Group 4). These classifications are intended to guide and assist the development of strategies for cancer prevention. The long-term goal is to publish evaluations of all environmental agents suspected as causes of human cancer, and to re-evaluate those for which evidence was incomplete when previously reviewed, whenever new findings provide additional evidence that may change a previous evaluation. These aims have not been modified since the competing application dated 28 June 1999.

**b. Studies and Results.** Two working group meetings to prepare volumes 84 and 85 of the *IARC Monographs* were completed during grant year 21 (1 Sept 2002 through 31 Aug 2003). Up-to-date lists of classifications, summaries of all evaluations, planned future activities, and related information have been posted on the *Monographs* website at <http://monographs.iarc.fr>, where they are freely available as soon as each volume is printed. From volume 1 (1972) through volume 85 (2003), the *Monographs* Programme has evaluated 890 agents and exposures in the human environment for evidence of carcinogenicity, many of them more than once as new scientific evidence relevant to evaluations of carcinogenicity has been published. An electronic version containing the complete, corrected text of all *Monographs* ever published has now been prepared (updated after each new volume is printed) from GMA Industries, Inc, Annapolis MD 21401 (<http://www.gmai.com>).

➤ **Volume 84, Some Drinking Water Disinfectants and Contaminants, Including Arsenic (15-22 October 2002) (in preparation).**

This volume supplements, but does not duplicate, *Monograph* volume 52 (1991) on chlorination and its byproducts. The new volume also evaluates chloramine, chloramidation, and certain chlorination byproducts not previously reviewed. It also addresses the serious problem of arsenic, found in drinking water. A brief summary of the meeting that is posted on the *Monographs* website at <http://monographs.iarc.fr> is attached as Appendix 1. Invited participants in the meeting are listed in Appendix 2.

➤ **Volume 85, Betel-Quid and Areca-Nut Chewing and Some Related Nitrosamines (11-18 June 2003) (in preparation).**

This volume evaluates various non-tobacco cultural habits that appear to pose a carcinogenic risk. Special emphasis is placed on habits that are practiced in certain developing countries, notably those in South Asia. An outline of the meeting is attached as Appendix 3. Invited participants in the meeting are listed in Appendix 4.

In addition to the two *Monographs*, two further meetings were convened during this period.

➤ **A scientific meeting** to prepare an IARC Scientific Publication on mycotoxins, including aflatoxins and fumonisins, and strategies for their control took place in Lyon in November 2002. This effort is an outgrowth of *Monographs* volume 82 and its reviews of aflatoxins and fumonisins. It was conducted jointly with other elements of the World Health Organization and the Food and Agriculture Organization of the United Nations. (This meeting and the resulting publication was not funded by the Cooperative Agreement, but is mentioned here for the sake of completeness in describing the *Monographs* Programme activities for the year.)

➤ **An ad-hoc Scientific Advisory Group** on priorities for future evaluations was convened in Lyon in February 2003 to review nominations of chemicals and complex chemical mixtures for evaluation by the *Monographs* Programme during the next five years. Nominations were solicited world-wide during the second half of 2002, making extensive use of the internet to reach the widest possible community of potential participants. (This meeting and the resulting publication was not funded by the Cooperative Agreement, but is mentioned here for the sake of completeness in describing the *Monographs* Programme activities for the year.)

**c. Significance.** The evaluations published in the IARC *Monographs* are intended to assist national and international authorities to formulate carcinogen risk assessments and to make risk management decisions, and to inform expert researchers as well as the general public regarding the evidence for carcinogenicity of environmental agents and exposures of all kinds.

**d. Plans** for the period from 1 Sept 2003 through 31 Aug 2004 include three volumes of the IARC *Monographs*:

- **Volume 86**, Some metals used in the hard metal and semiconductor industry (October 2003).
- **Volume 87**, Lead and lead compounds (February 2004).
- **Volume 88**, Smokeless tobacco (June 2004).

In addition to the three *Monographs* working groups, a further meeting is planned to complete the IARC Scientific Publication on mycotoxins. (This meeting and the resulting publication is not funded by the Cooperative Agreement, but is mentioned here for the sake of completeness in describing the *Monographs* Programme activities for the year.)

**e. Publications**

IARC (2002) *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, Volume 81: Man-Made Vitreous Fibres.

IARC (2002) *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, Volume 82: Some Traditional Herbal Medicines, Some Mycotoxins, Naphthalene and Styrene.

Principal Investigator/Program Director (Last, first, middle): COGLIANO, Vincent James

IARC (2003) Report of an Ad-Hoc *IARC Monographs* Advisory Group on Priorities for Future Evaluations, IARC Internal Report No. 03/001.

IARC (in preparation) *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, Volume 83: Tobacco Smoke and Involuntary Smoking.

IARC (in preparation) *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, Volume 84: Some Drinking Water Disinfectants and Contaminants, including Arsenic.

IARC (in preparation) *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, Volume 85: Betel-Quid and Areca-Nut Chewing and Some Related Nitrosamines.

**f. Project-generated resources.** The *IARC Monographs* are published and distributed to government agencies and scientific libraries. Summaries are available on the internet at <http://monographs.iarc.fr>.

**PROGRESS REPORT SUMMARY – Addition to page 14**

**Will there be, in the next budget period, a significant change in the level of effort for key personnel from what was approved for this project?**

Name	Level of effort year 21	NCI funding year 21*	Level of effort year 22	NCI funding year 22*	Remarks
J M Rice	(b)(4), (b)(6)				Retired 31 October 2002
R Bann					
Y Grosse					Now funded entirely from other sources
K Straif					
C Partensky					Retired 31 January 2003
B Secretan					Increase in effort
D McGregor					Expiration of contract
V J Coglianò					Hired as head of programme March 2003
F El Ghissassi					Hired to assist in checking of <i>Monographs</i> . 50% funded from other sources.

\*NCI funding is % of level of effort (previous column) paid by NCI grant