

## Annex II: Progress report

### Progress Report

<b>Title of the project</b>		
Development of analytical methods for biological monitoring of exposure to carcinogenic substances		
<b>Acronym of the project</b>		
B I O M O N E C S		
		<b>Total project cost</b>
<b>Type of contract</b>		€ 918 000.00
CRAFT		
<b>Contract number</b>	<b>Duration</b>	<b>EU contribution</b>
QLK4-CT-2002-71801	24 months	€ 459 000.00
<b>Commencement date</b>		<b>Period covered by the progress report</b>
April 1 <sup>st</sup> , 2003		1 April 2003 - 29 February 2005
<b>PROJECT COORDINATOR</b>		
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<b>Key words</b>
Biomonitoring, analytical chemistry, occupational and environmental health, carcinogens
<b>World wide web address</b>
<a href="http://www.biomonecs.com">www.biomonecs.com</a>

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## Section 2: Project Progress Report

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### Objectives:

Conversion of advanced low level quantitative laboratory methods into standardised routine methods for the analysis of biomarkers derived from a selection of 10

carcinogenic substances (class I biomarkers) and evaluation according to specific pre-established performance criteria of these methods in routine laboratories under a regime of high level quality assurance in compliance with ISO 25/EN45001;  
Development of new low level standardised laboratory methods for analysis of another 11 new biomarkers derived from carcinogenic substances (class II biomarkers) and after establishment of performance parameters, implementation of a selection of these methods in routine laboratories under a regime of high level quality assurance (reduce time for analysis by 50 %, reduce costs per analysis by 50 %)  
Preparation of detailed technical documentation/specifications for the application of the 21 biomarkers by the advisory board, consisting of representatives of SMEs, RTDs and external experts, as part of the service packages which will be supplied to the user (health care professional) the end-user (industry, governmental health authorities)  
Introduction of a BIOMONECS service package for reliable biomonitoring of 21 carcinogenic substances (10 class I and 11 class II biomarkers) to the (end-)user in at least four EU member states: B, D, UK, NL). If possible, the consortium of SMEs will be extended by including routine labs from other EU-member states.

### **Results and Milestones:**

In the first phase of the project analytical methods were introduced in the routine labs for the following 10 carcinogenic substances (class I biomarkers): arsenic, benzene, cadmium, chromium, cyclophosphamide, di(ethyl)hexylphthalate, hexavalent chromium, nickel, platinum, and polycyclic aromatic hydrocarbons. The RTD-performers assisted the routine labs during the implementation process by providing reference standards, by exchange of test samples and by preparing documentation. After implementation of the methods the routine labs participated in an external quality assurance programme provided by one of the RTD-performers. To evaluate the service in practice, fourteen pilot studies were undertaken in several countries. During the pilot studies RTD-performers provided technical assistance and gave support reporting on the outcome of the analyses to the user and end-user. After finishing the pilot project the user was asked to complete a questionnaire to evaluate the service.

In the second phase of the project methods for another 11 carcinogenic substances were implemented in routine labs: acrylamide, aniline, benzidine, benzene, beryllium, chloroform, ethylene oxide, o-toluidine, propylene oxide, tetrachloroethylene, and trichloroethylene. The service provided for these biomarkers was set up and tested in the same way as for the class I biomarkers.

A website ([www.biomonecs.com](http://www.biomonecs.com)) was launched containing information on the project and the services provided by the BIOMONECS consortium. Biological Application DataSheets (BADS) with concise information on the toxicity of the carcinogenic substance and the possibilities for biological monitoring using one or several different biomarkers were prepared.

A Generic Biological Monitoring Study Protocol (GBMSP) with guidelines for the practical enrolment of a study. Study plans were prepared to specify the services that were provided by the routine lab. Based on this information the routine lab would prepare a quotation for the costs involved in the service. After completing the pilot study a report was prepared, describing the results of the biological monitoring campaign.

For all biomarkers that were implemented in routine labs background levels were determined in 60 non-smoking male and female subjects with low occupational exposures. These data will be used by the SME routine labs for reference purposes.

**Benefits and beneficiaries:**

The benefits of this project so far are:

More than twenty biomarkers for carcinogenic substances are available in routine labs  
A complete service for biological monitoring campaigns is provided to users and end-users

Information about this service is available on the internet

The beneficiaries in this project are:

**Users:** Occupational physicians, occupational hygienists and safety engineers have been able to improve their performance in supporting the end-users. Biological monitoring helps them to deal with exposure to carcinogenic substances.

**End-users:** Employers and workers in the public and private sector (end-users) have had access to an improved strategy for exposure assessment. For substances that are taken up by inhalation, air measurements may provide useful information. However, in those cases when the workers are wearing respiratory protection it is difficult to verify how effective this equipment is. Also, many chemical substances are also taken up through the skin or via the gastrointestinal tract. This exposure would not be identified using only air monitoring. In most cases the analyses of biological materials revealed no work-related exposure, suggesting that workers handling these substances were adequately protected. In some other cases workers handling carcinogenic substances were found to be exposed to these substances. Experts in biological monitoring supported the occupational hygienists and physicians (users) to relay the outcome of biological monitoring studies to the management and workers (risk communication) and helped to identify possibilities for technical and organisational improvements to further reduce exposure to carcinogenic substances.

**Future actions (if applicable):**

During this project a service for biological monitoring of carcinogenic substances was developed and tested in a limited number of EU member states. It is useful to provide the service also to other EU member states. To support this development the consortium may be enlarged and include new partners (routine labs and universities) in those countries.

Documentation for each carcinogenic substance for which a biological monitoring service has been established will be published in concise data sheets (BADS).

A generic protocol for biological monitoring studies (GBMSP) including information on ethical issues related to biological monitoring will be published in a peer review journal.