

Information leaflet for adults

General Biomonitoring survey in Luxembourg



“General Biomonitoring Survey in Luxembourg to evaluate prioritised harmful chemical substances exposure under the European Partnership for the Assessment of Risks from Chemicals (PARC)”

Dear Sir/Madam,

You and your child are invited to take part in this survey. Before you decide whether you wish to participate, please read the following information to understand why the survey is being done and what your participation involves. We are happy to answer any questions or concerns you may have. Your participation is voluntary, and you may withdraw at any time.

1) What is this survey about?

The **General Biomonitoring Survey in Luxembourg** is part of a broad project named the **European Partnership for the Risk Assessment of Chemicals (PARC)**. PARC is a 7-year project under Horizon Europe— a framework programme of the EU for funding research and innovation. PARC is funded by the European Commission and national governments and includes experts from 28 countries and EU agencies. The overall goal of PARC is to develop better risk assessment tools for chemical products in order to protect human health and the environment. The General Biomonitoring Survey in Luxembourg is under the responsibility of the Health Protection Department at the **Laboratoire national de santé (LNS)**.

2) Why PARC is important for our public health?

We are all exposed to a complex mixture of chemicals in our daily lives. Some chemicals may harm health and for this reason, they must be regulated in the environment, consumer products, food, and drinking water. PARC aims to understand human exposure to such chemicals and the related health risks by using **human biomonitoring** (measurements of environmental chemicals or their reaction products in biological samples collected from people).

The results will be used to support policymakers with their decisions regarding the introduction or adaptation of relevant laws and interventions for the safe management of chemicals and the protection of human health in Europe. Learn more at www.eu-parc.eu

3) Who approved this survey?

The survey has been approved by the municipality, *Service de Médecine scolaire*, and *Ministère de la Santé et de la Sécurité sociale*. Moreover, the *Direction de la santé (DISA)* and *Comité National d’Ethique de Recherche (CNER)* issued favourable opinions. Ref. n° 84cx5bba4.

4) Why you are asked to take part?

You and your child have been randomly selected to represent adults and children from the **general population** in Luxembourg. By agreeing to take part, you can help to ensure that people like you are properly represented in the survey results. This is important for making the survey more reliable and useful.

5) How will the survey be carried out?

The survey will take place from 2025-2027 in Luxembourg and other 23 European countries. In Luxembourg, it will include a total of 300 adults and 300 children. Each adult participant will provide a **biological sample** of **urine** and **blood** and will complete a questionnaire. Each child participant will provide a biological sample of **urine**, **blood**, and **hair**. We will analyse your sample to assess your and your child's exposure to the following chemicals: **plasticisers**, **metals**, **pesticides**, **mycotoxins**, and per-and polyfluoroalkyl substances (**PFAS**). Moreover, we will collect

environmental samples of **dust**, **indoor air**, and **tap water** from your home to evaluate the chemicals in the indoor environment.

6) What do you have to do if you agree to take part?

If you **agree to participate**, please scan the **QR code** provided on the last page. It will lead you to the **LNS webpage** where you can also ask any additional questions you might have. Your response is kindly requested within 30 days from the date of receipt. If you do not want to participate, you can help us improve future studies by scanning the QR code provided and answer a few optional questions completely anonymously, you can help us to understand how the people who choose not to take part in the survey compare to the people who want to take part.

7) What happens after we receive your positive answer to participate?

Once you fill the form provided in the LNS website, we will confirm if you are eligible to participate in the survey.

a) If your participation is **confirmed**, we will contact you to agree on a suitable date for your appointment with our LNS Health Protection Department team at your home. You will be asked to confirm your willingness to participate in the survey by completing and signing the enclosed consent form in duplicate. You will keep one copy for your records and we will keep the other for our records. You can ask any questions you wish and you can take the time you need to clarify any concerns prior to signing. Prior to the appointment, you will receive a reminder with notice of any preparations required beforehand.

b) If you do **not** fulfil the eligibility requirements or the maximum participation limit of this survey has been reached by the time we receive your form, you will be informed about it.

8) How do you have to prepare for the appointment?

Special preparations are necessary before the day of the visit. You will receive a kit by post to collect a morning urine sample. Additionally, you will be asked not to vacuum for 14 days and not to ventilate the house for 24 hours before the visit to ensure the collection of high-quality environmental samples.

9) What will happen during our appointment?

Our team from the LNS Health Protection Department will visit you and your child at home. You must complete and sign the **consent form** (both legal guardians must provide consent for your child). Additionally, your child will sign an **assent form**. Our nurse will collect a blood sample from both you and your child, as well as a small sample of your child's hair (i.e., 1cm² of hair on the scalp area). The team will collect dust and air samples from your living room, kitchen, your bedroom, and your child's bedroom. They will also collect the urine sample that you collected in the morning. For the blood sample, you can expect to feel the same sensations as with any other blood draw, such as slight pain when the needle is inserted. All of our nurses are highly experienced in these procedures. Our nurse will collect a total quantity of 18 mL of blood from you and a total quantity of 5.4 mL of blood from your child. Please discuss any concerns you have with the nurses on the sampling day, and inform them of any discomfort you might experience. Furthermore, you will need to fill out a **questionnaire** that includes questions about the sample collection, sociodemographic details, diet, lifestyle, environmental and occupational chemical exposure, and health status. The entire appointment will take approximately 2-3 hours.

10) What will happen to your samples, data and results?

Your samples and data will be used only according to your informed consent and in a way that protects your privacy according to the European regulations GDPR (Regulation (EU) 2016/679) and EUDPR (Regulation (EU) 2018/1725) and national laws. The released results of the survey will not identify you in any way.

All the data will be stored in a database and will be previously **pseudonymised**. This means that a code will be used to remove your personal identifiable information to protect your privacy. Information which identifies you (name, contact details) will be kept separately and under protective measures at the LNS Health Protection Department. Your pseudonymised samples (blood, urine, and hair) will be transferred to the LNS for analyses. For

chemical analyses that are not conducted at the LNS, some of your samples will be sent to partner laboratories within the PARC consortium located in other EU countries. After the analyses, the remaining samples will be stored at the LNS for 10 years and may be used in future analyses related to PARC project to study other chemical exposure if you choose so in the consent form for secondary use. This secondary use will be subject to obtaining a favourable opinion from DISA and CNER, as well as authorisation from *le ministère de la Santé et de la Sécurité sociale*. After 10 years, the samples will be destroyed. Please note that a request for authorisation for secondary use of pseudonymised samples will be made if your child reaches the age of majority. The pseudonymised data will be used for scientific purposes and may be combined with other data from different sources and shared among PARC partners. The sharing of data, but never your personal data, will be facilitated through dedicated and secure data infrastructures and/or Information systems within PARC. Only pseudonymised or aggregated data (i.e., anonymous) will be used for any publications of study results and **no individual data** will be passed on (by individual data, we mean specific information about a single person). The data will be entered into the VITO central database (Personal Exposure and Health (PEH) data platform), which has restricted access. Only PARC partners can access the data upon request. Data on the results of the chemical analysis of your samples will be shared with IPCHEM, (which is the European Commission Information Platform for Chemical Monitoring, <https://ipchem.jrc.ec.europa.eu/>). These data will undergo an additional step of pseudonymisation (double coding). Moreover, summary statistics will be published in the European Human Biomonitoring dashboard (<https://hbm.vito.be/eu-hbm-dashboard>). Data will be kept in a pseudonymised way until the finalisation of the PARC project, afterwards, it will be anonymised. The LNS Health Protection Department will retain the anonymised data for an additional 10 years, after which it will be deleted.

The overall results of the survey will be provided to national and European authorities to support policy actions related to chemical management for public health protection and will be published in scientific journals. They will also be disseminated to other stakeholders, including the general public, scientists and other interested parties. Reports published from the survey will not include information that can be traced back to you; this will be achieved through an aggregated approach, grouping data by country for maximum anonymity. Please understand that data sharing with the EU agencies and IPCHEM is essential to develop European policies regarding chemicals, and that your participating in the project also means sharing these data.

11) How can you learn about the results of the survey?

You will receive a **report** containing the results of the environmental assessment conducted in your home, along with some recommendations. Moreover, you will be informed about the national collective results from the chemicals in the biological samples once the survey is finished. You will be kept informed of the latest updates regarding this survey through newsletters, information campaigns, and the PARC project website.

12) How will your privacy be protected?

Your and your child's privacy is protected by complying with the requirements of the European General Data Protection Regulation (GDPR). The LNS is responsible for the protection of the data against loss, unauthorized access/use, modification/disclosure, or other misuse. The **Data Controller** is the LNS, through its Health Protection Department. Our **Data Protection Officer** is at your disposal for questions or concerns related to data protection and may be reached at the following contact information: Quentin Roger (dpo@lns.etat.lu). The processing of your and your child's data is based on article 6(f) of the GDPR. You can revoke your consent to the collection and processing of the data at any time without giving reasons. After your revocation, no further data will be processed. You may lodge a complaint with the *Commission Nationale pour la Protection des Données* (CNPD) if you feel that your rights have not been respected.

13) Why do we need your written consent?

Your written consent, both for yourself and your child, confirms your voluntary participation in the survey after **comprehending the requirements and your rights**. You have the right to withdraw your and your child's

participation without any consequence at any point (including any data or samples already provided, if they have not been completely anonymised and so impossible to be traced back, and if the samples are still not analysed). Additionally, you have the right to choose if you want to receive the results or not. Your confirmation also includes granting permission for future contact, whether it be to communicate the results or for historical, statistical, or scientific purposes.

14) How will you benefit if you participate?

You will receive the **results of the environmental assessment of your home** (if you wish) with our recommendations. You will not receive individual results of the biological samples. However, if elevated levels of chemicals, which may pose a health risk, are detected, you will be notified and advised to discuss your results with a medical doctor-unless you have explicitly indicated a preference not to receive such information on your certificate of informed consent. You and all citizens in Luxembourg and Europe will benefit from the collective results of the survey, which will be used to develop better chemical management policies across Europe at a population level. To thank you for participating, we will give you a present and voucher for you and your child with a value of 80€.

15) Are there any risks if you join the PARC survey?

Some participants may experience **minor discomfort** during the collection of blood samples. Blood samples are collected invasively (using conventional blood tubes) by qualified and specially trained nurses. As with any blood sampling, symptoms such as pain at the puncture site, hematoma at the puncture site, circulatory problems, vagal discomfort, nausea or infection may occur. Our nurses will utilise anaesthetic patches and specialised needles designed for children to ensure maximum comfort during the procedure. Hair samples are also taken by trained staff. Urine samples are taken by yourself. Survey participants will be **covered by insurance** for any adverse events relevant to their participation, without any charge.

16) Are there any costs to you?

No, the survey will be conducted at no cost to you. Your participation is entirely voluntary.

17) What if you have any concerns or complaints while you are taking part in the survey?

Your and your child's wellbeing is our foremost priority and we will take all necessary precautions to ensure comfort and safety. If you have any concerns during your appointment, please discuss them with our team or at any time by contacting the **Principal Investigator (PI)**: Dr Maria Torres Toda (medi-surveys@Ins.etat.lu), +352 28100 660. You have the right to opt out of the survey for any reason (without the need to disclose this) without any consequences to you.

18) What happens if you say yes, but change your mind later?

You and your child are **free to withdraw** from the survey, without any consequences by sending an e-mail to Dr Maria Torres Toda (medi-surveys@Ins.etat.lu) or orally by calling us (+352 28100 660). We will, however, retain the right to use any samples collected before the withdrawal in a confidential manner (i.e., anonymised) if it is not possible to remove the data anymore (i.e., data already published). If the samples have not been used yet, you can request their destruction. The withdrawal of your consent as well as the refusal of your participation will not involve any disadvantage for you.

The results will be used to support policymakers with their decisions regarding the introduction or adaptation of relevant laws and interventions for the safe management of chemicals and the protection of human health in Europe. Learn more at www.eu-parc.eu.

Please scan the QR code below for more information or visit the following website:



Thank you for reading this leaflet and for considering to join the General BM Survey in Luxembourg!

Sincerely,

Health Protection Department Team

Laboratoire national de santé

1, 3555 rue Louis Rech,

L-3555 Dudelange, Luxembourg