LAYMAN'S REPORT

LIFE APEX

Systematic use of contaminant data from apex predators and their prey in chemicals management

LIFE17 ENV/SK/000355

www.lifeapex.eu

LIFE APEX Project

Layman's Report Contents

The LIFE APEX project has received funding from the European Union's LIFE programme under the grant agreement LIFE17 ENV/SK/000355

PROJECT DATA

Project number: LIFE17 ENV/SK/000355

Project location: DE, GR, IT, NL, SK, UK

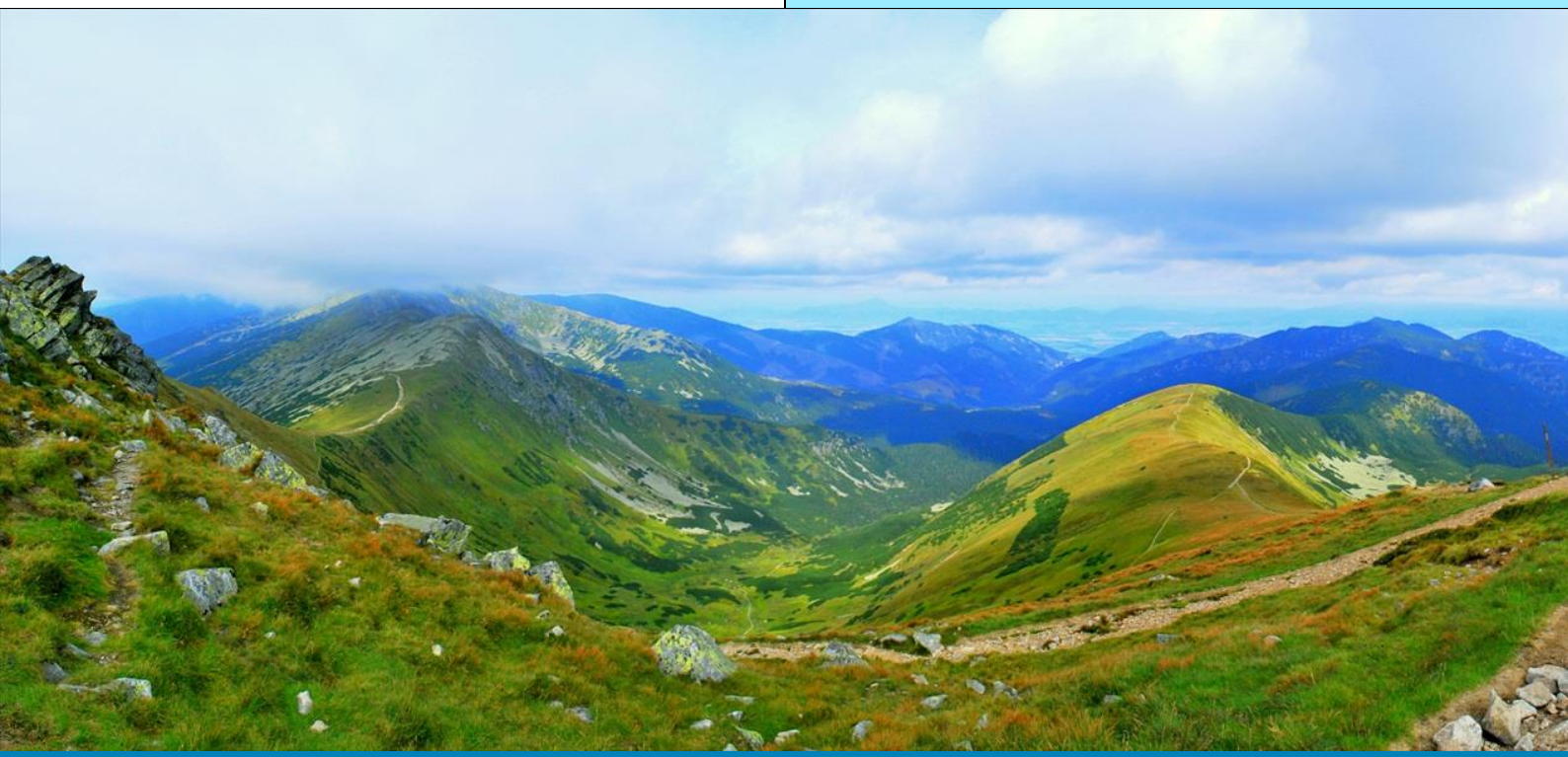
Total budget: € 3,353,413.00

EU contribution: € 2,012,047.00

Duration: 01/09/2018 - 31/08/2022

PROJECT PARTNERS

	Environmental Institute
	German Environment Agency
	Naturalis Biodiversity Center
	National and Kapodistrian University of Athens
	UK Centre for Ecology & Hydrology
	University of Florence
	Fraunhofer Institute IME



1. INTRODUCTION

Chemicals are used and released by industry, medicine, energy generation, agriculture and other processes essential for maintaining health, nutrition and well-being. Chemical development, manufacture and use are also important wealth generators, with global chemical sales projected to reach c. $8500 billion by 2030 (OECD 2012). Europe's chemical industry is the third largest production sector in Europe and total EU28 chemicals sales (excluding pharmaceuticals) reached €615 billion in 2015 (CEFIC 2017).

The manufacture and use of chemicals comes with a potential cost however as it leads to environmental emissions. A significant proportion of chemicals produced in the EU28 are classed as 'harmful to the environment' and/or 'toxic' as defined by EU regulation. According to Eurostat (2014 data), EU28 production of 'environmentally harmful chemicals' (defined as chemicals harmful to the aquatic environment) has been around 135–150 million tons/annum for the period 2004–13, representing around 41-45% of all chemicals produced, and EU28 production of 'toxic chemicals' was 200 million tons (62.7% of all chemicals produced) in 2013. Production of the most toxic carcinogenic, mutagenic and reprotoxic (CMR) chemicals was 30.7 million tons (9.5% of all chemicals produced) in 2013.

The conundrum is how to benefit from chemicals without contaminating the environment and causing a risk to the health of wildlife and human health. Environmental protection is primarily driven through pre-market measures to assess hazard, exposure and risk prior to authorising sale, and post-market measures to further assess, monitor and manage risk once chemicals are in use. Such measures are governed by EU legislation, including REACH and the Biocidal Products Regulation (BPR). There is a particular focus on chemicals that are persistent / very persistent (P/vP) bioaccumulative / very bioaccumulative (B/vB) and toxic (T), because such PBT (persistent, bioaccumulative, toxic) chemicals are not readily degraded and have the potential to accumulate along the food chain, leading to exposure of wildlife and humans.

Apex predators are particularly well suited to contaminant monitoring for risk assessment (RA) and management because: (1) being at the top of the food chain and relatively long-lived, they strongly bioaccumulate PBT chemicals; (2) they integrate contaminant exposure over time and over relatively large areas; (3) most species are relatively easily collected and sampled; (4) populations can be easily monitored and quantified.

LIFE APEX addresses several EU policies, while focussing on REACH and BPR. LIFE APEX supports the aims of REACH and BPR in protecting the environment and human health from harmful chemicals. LIFE APEX consequently contributes to the aims of other EU policies that incorporate protection of the environment and human health from harmful chemicals. This includes policies on the non-toxic environment incorporated within the 7EAP and the Circular Economy and measures to secure the good ecological status of freshwaters under the Water Framework Directive (WFD), and of good environmental status of marine waters under the Marine Strategy Framework Directive (MSFD). In particular, LIFE APEX can contribute to achieving protection of apex predators, which is a goal of both the WFD and MSFD.

The main expected impact is reduced human and wildlife exposure to harmful substances, protecting human health and the environment. This will be achieved over the longer-term through:

(1) Improved chemical risk management by regulators resulting from substantial use of apex predators and prey (AP&P) chemical monitoring data for cost-effective: (a) detection of chemicals in the environment; (b) prioritisation of these chemicals in the environment for hazard assessment; (c) assessment of effectiveness of risk mitigation measures; and (d) determination of predominant mixtures in the environment.

(2) Wide engagement of Environmental Specimen Banks (ESBs), Natural History Museums (NHMs) and other collections and labs in generating high quality contaminant data from AP&P samples.

(3) A growing body of available, accessible, comparable and interoperable contaminant data from AP&P, attuned to regulatory needs.

2. METHODOLOGY

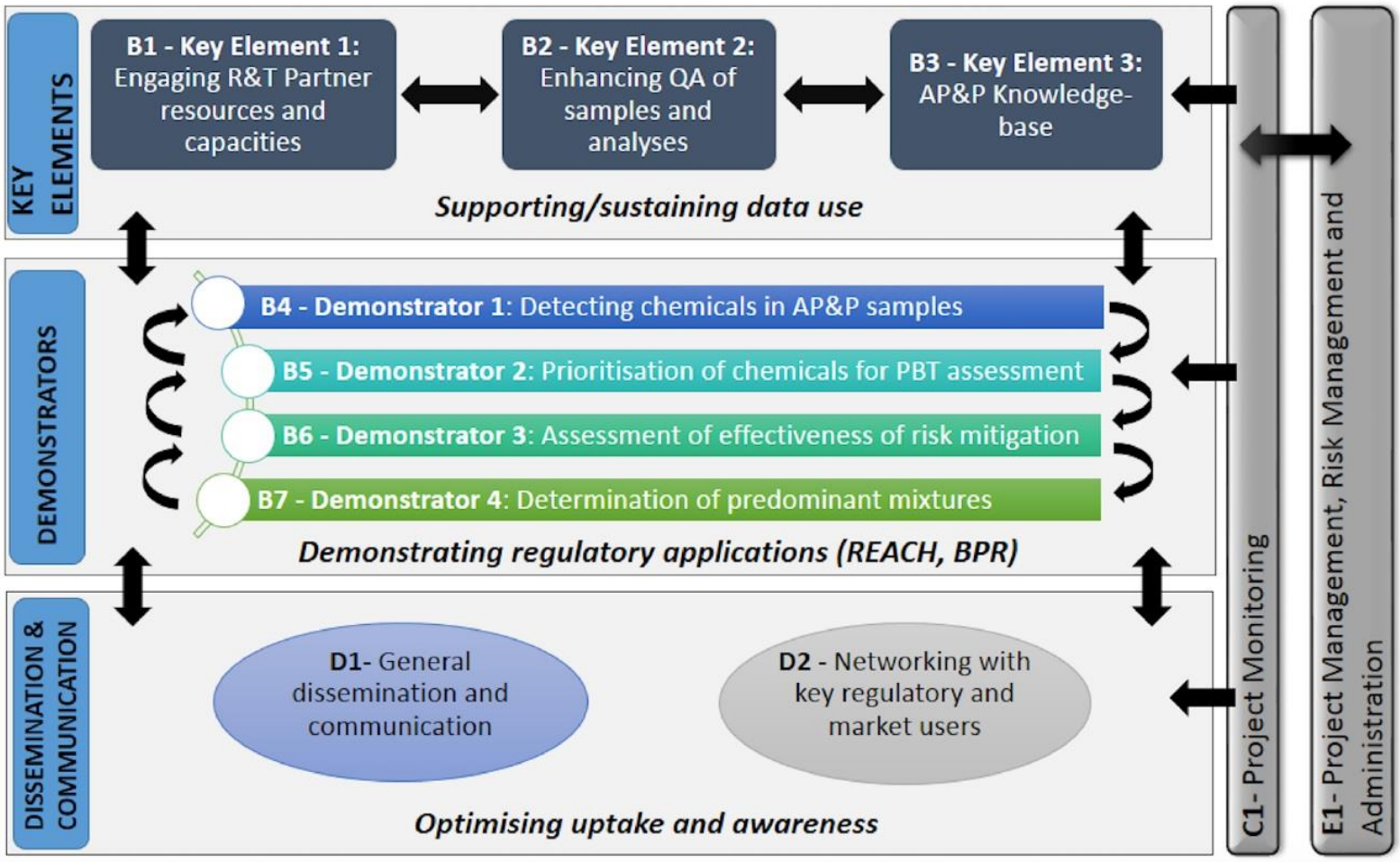
KEY ELEMENTS

B1	Engaging key Replication and Transfer (R&T) Partner Assessing R&T Partners resources
B2	Reviewing and harmonizing quality assurance for Apex predator and prey (AP&P) sampling, processing and archiving
B3	Enhancing access to relevant AP&P samples and related contaminant data → Apex Knowledge base

DEMONSTRATORS

B4	Revealing presence of chemical contaminants in AP&P samples through target and NTS analyses
B5	Prioritisation of the most relevant contaminants in AP&P samples and assessment of applicability of such monitoring data for PBT assessment
B6	Demonstrating the use of raptor chemical monitoring data to assess impact and effectiveness of risk mitigation measures
B7	Defining predominant chemical mixtures in AP&P samples

C1	Monitoring the impact of the project actions in relation to the specified performance indicators
D1	Development of general dissemination and communication strategy and implementation of strategy's actions
D2	Networking with key users to promote regulatory and market uptake of LIFE APEX approaches and outputs
E1	Project management, risk management and administration and After-LIFE Plan

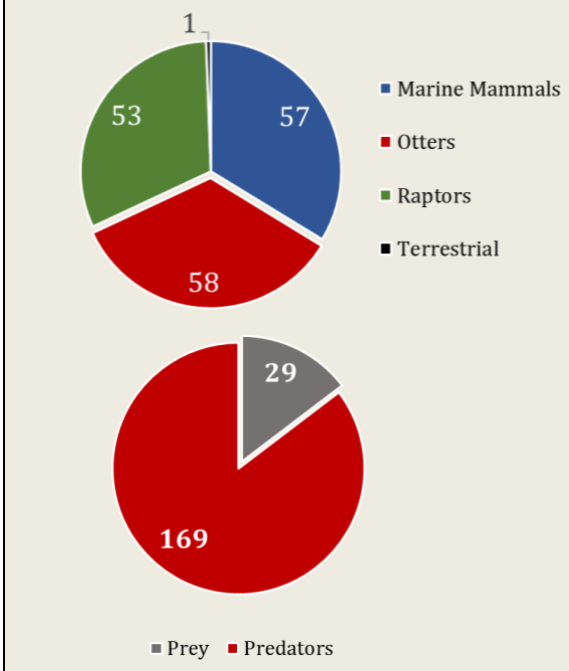


3. RESULTS

LIFE APEX results show that the cutting-edge suite of analytical and statistical approaches deliver robust data that can provide rapid, early warning on bio-accumulating contaminants in apex predators and/or contaminants that are occurring at concentration levels warranting further attention. LIFE APEX concluded analysis in the frame of project methods used:

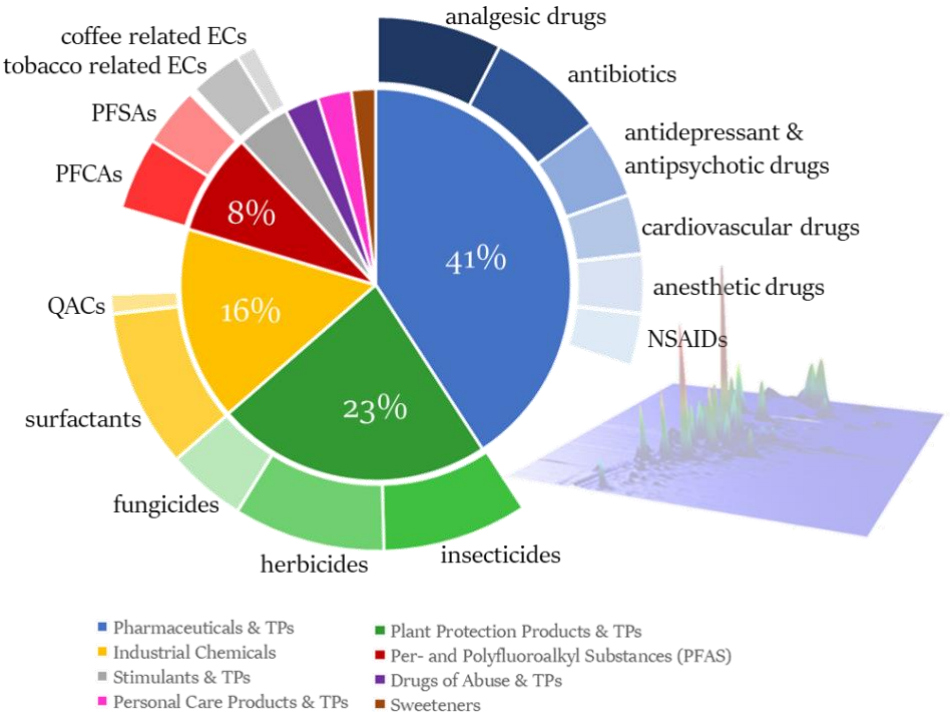
Tier 1: Wide-scope screening - (67 samples from UK, DE, NL, SE)
Tier 2: Time trend analyses - (68 samples from DE, UK)
Tier 3: Replication with R&T partners - (63 samples from R&T countries: SE, DE, IT, FR, AT, UK, DK, CZ, NO, HU, ES, UA, PL, BE, SI, PT, RO, SK, GR)

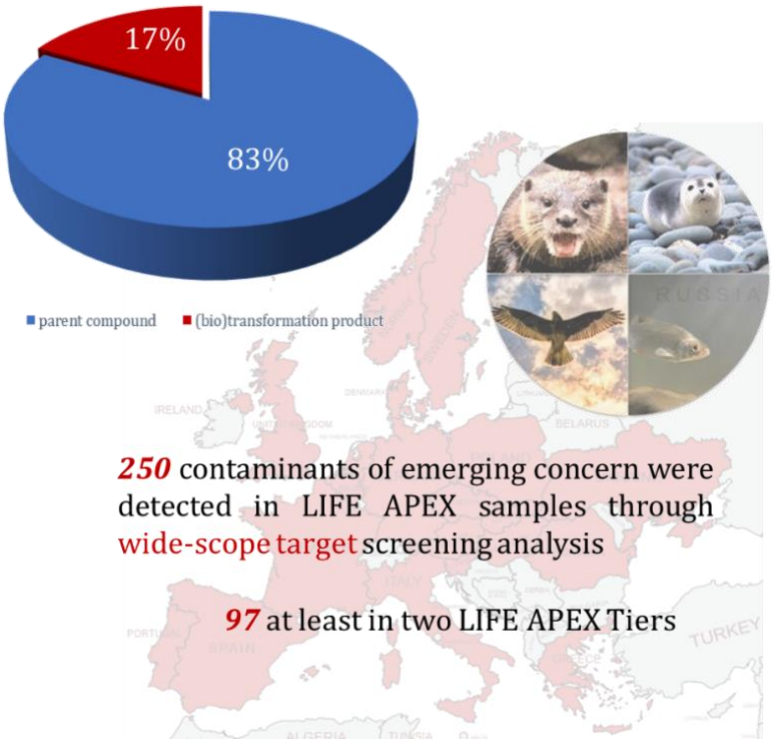
LIFE APEX (ALL TIERS: Tier 1, Tier 2, Tier 3):
European sample coverage of apex predator samples / Final number of detected compounds



198 apex predators & prey samples
20 European countries

pan-European biomonitoring study

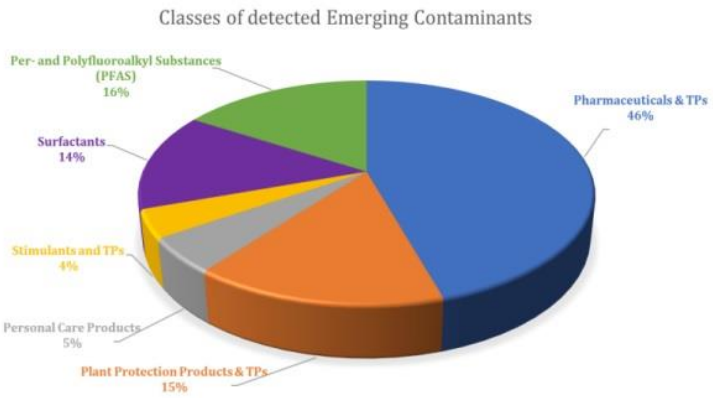

analgesic drugs
antibiotics
antidepressant & antipsychotic drugs
cardiovascular drugs
anesthetic drugs
NSAIDs
insecticides
herbicides
fungicides
surfactants
QACs
PFCAs
PFSAs
coffee related ECs
tobacco related ECs
41%
23%
16%
8%
Pharmaceuticals & TPs
Industrial Chemicals
Stimulants & TPs
Personal Care Products & TPs
Plant Protection Products & TPs
Per- and Polyfluoroalkyl Substances (PFAS)
Drugs of Abuse & TPs
Sweeteners

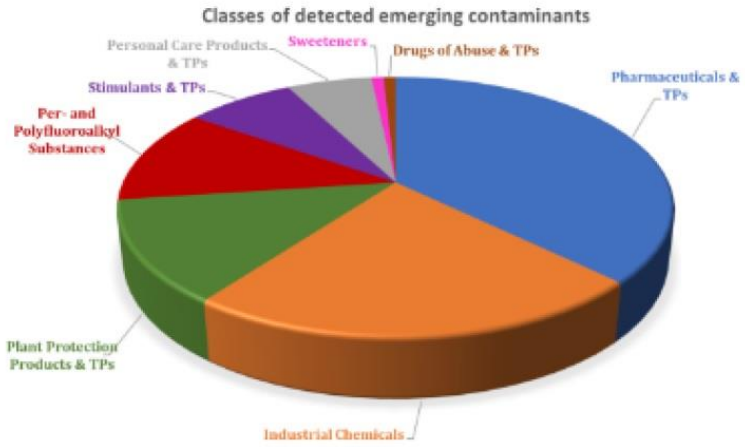

17%
83%
parent compound
(bio)transformation product
RUSSIA
BELARUS
IRELAND
TURKEY
250 contaminants of emerging concern were detected in LIFE APEX samples through wide-scope target screening analysis
97 at least in two LIFE APEX Tiers

Results from wide-scope target analysis in **Tier 2** LIFE APEX samples.

- ✓ In total, **99** ECs were detected in LIFE APEX samples (Tier 2)
- ✓ **Pharmaceuticals & TPs** → **46%**
- ✓ Per- and Polyfluoroalkyl Substances (PFAS) → **16%**
- ✓ Plant Protection Products & TPs → **15%**
- ✓ Surfactants → **14%**
- ✓ Only **10** ECs were detected with ***% frequency of detection > 60***

↳ difficult task → time trend analysis using biota samples





- ✓ In total, ***118*** CECs were detected in Life APEX samples (Tier 3)
- ✓ **Pharmaceuticals & TPs** → **37%**
- ✓ Industrial Chemicals → **23%**
- ✓ Plant Protection Products & TPs → **13%**
- ✓ Per- and Polyfluoroalkyl Substances (PFAS) → **12%**

- Same trend for PFAS detection as observed in previous Tiers→ higher concentrations in otters compared to marine mammals and raptors
- Otters from UK→ significant higher cumulative concentration of PFAS, especially l-PFOS
- Pharmaceuticals were detected in high concentrations in Buzzard samples, indicating potential medical treatment before death

Monitoring: How many samples and how often?

As part of the Life Apex B6 demonstrator we have been carried out Pan-European analysis of current chemicals of concern, the aims being:

- (1) to characterise exposure and risk that these contaminants pose to raptors and the wider environment
- (2) to explore the design of monitoring programmes to effectively and efficiently detect temporal trends in these contaminants

For our demonstration of monitoring at the pan-European scale (Task B6.4) more than 125 Common Buzzard (*Buteo buteo*) liver samples from 17 institutions in 11 countries, allowed 63 pooled samples to be prepared for multiple targeted analyses. The time period of samples was from 1998 to 2021, varying by country.

Factors that can increase variability within annual results include: age, sex (through differing diets or off-loading of contaminants into eggs) and nutritional status of the bird. Despite not restricting these factors within the sampling strategy, Monte Carlo based power analysis has shown that even relatively small time trends in concentrations can be detected over likely monitoring time periods (5 or 10 years).

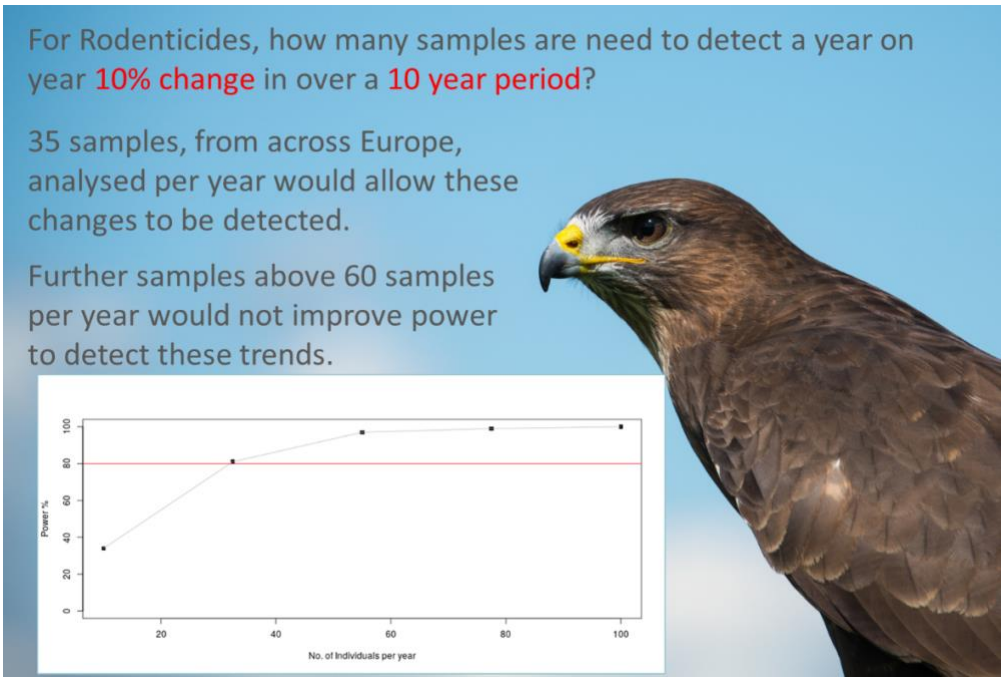


Figure 1

Comparisons among contaminants using the same pooled liver samples (2-3 individuals) from 11 countries across Europe indicated that the inherent variability in exposure differed between contaminants and that this in turn affects our power to detect temporal changes in these datasets.

For example (Fig. 2), a similar number of samples analysed per year for sum Polybrominated Diphenyl Ethers (SumPBDEs) allowed smaller changes (5% per year) to be detected in a shorter period of time (over a 5 year period) than for sum Second Generation Anticoagulant Rodenticides (SumSGAR; 10% change per year over a 10 year period).

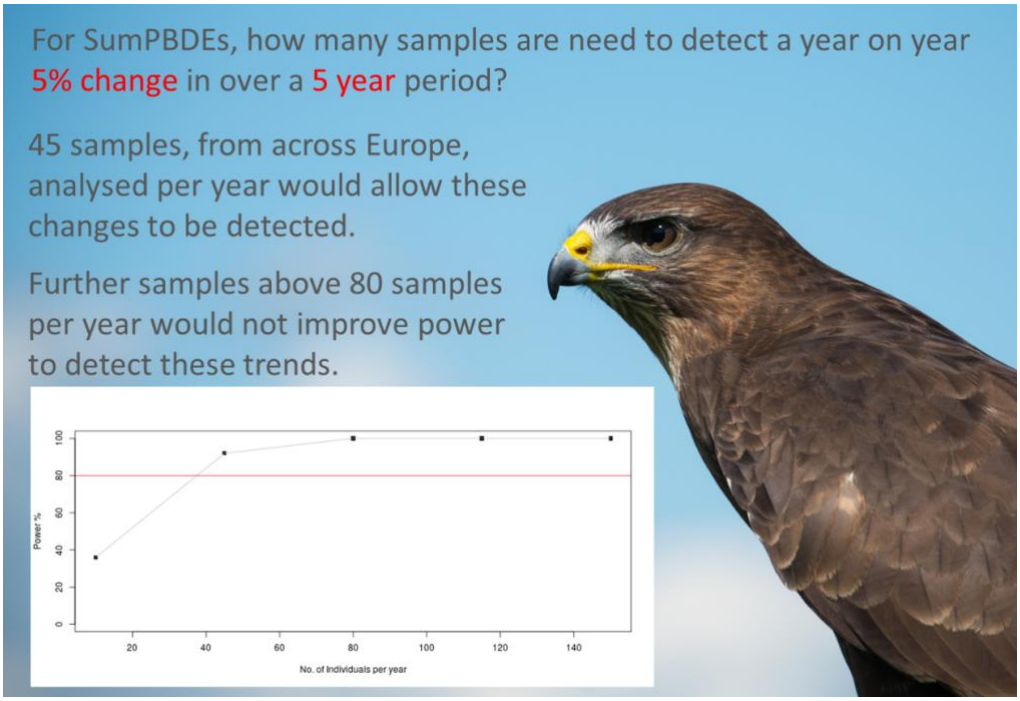


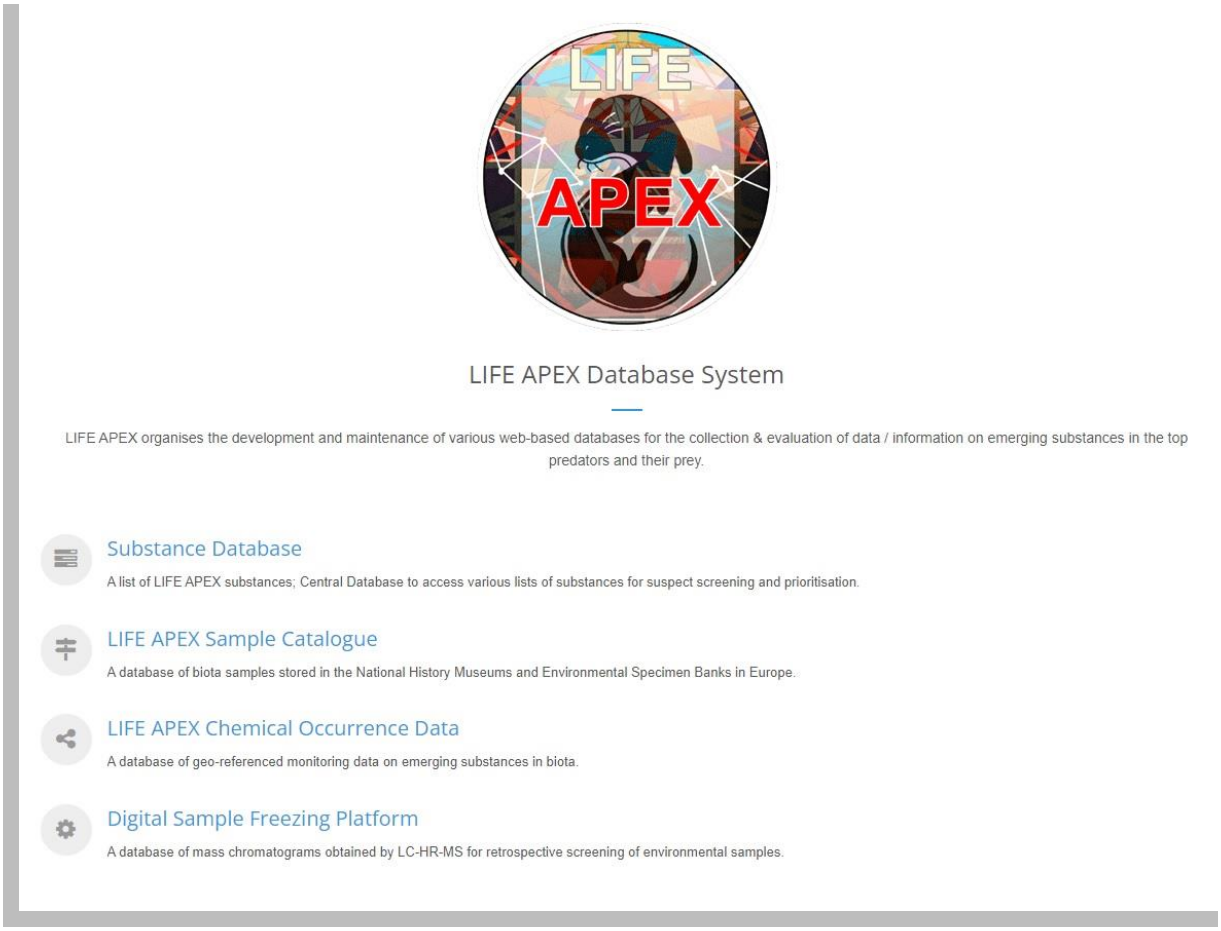
Figure 2

More information on LIFE APEX results can be found on:

https://lifeapex.eu/dissemination/ and

https://lifeapex.eu/publications/

LIFE APEX Database



The LIFE APEX Database:

- Module 1 - LIFE APEX Sample Catalogue of LIFE APEX Database System contains 104 entries, with the data on samples from the NHMs and ESBs in Europe.
- Module 2 - LIFE APEX Chemical Occurrence Data contained 953,444 data entries for 3,253 substances as of the beginning of October 2022.
- Module 3 - HRMS chromatograms of all 198 analyzed samples of Tier 1 (67), Tier 2 (68) and Tier 3 (63) were uploaded to NORMAN Digital Sample Freezing Platform (DSFP), which enabled suspect screening of environmentally relevant pollutants from the NORMAN Substance Database in all raw chromatograms.

4. LONG-TERM ENVIRONMENTAL BENEFITS

The main impacts of the project on the environment are indirect but nonetheless clear, substantial, ambitious and credible. Better use of chemical monitoring data, in order to (a) detect which chemicals that are present in the environment, (b) determine which chemical mixtures predominate in the environment, (c) prioritise substances for hazard assessment and (d) assess effectiveness of risk management measures (RMM). Together these actions support ECHA and MSCAs to identify hazardous substances more rapidly and subject these substances to appropriate RMM sooner, thus reducing exposure of humans and wildlife to harmful substances.

A more efficient prioritisation of hazardous substances and improved knowledge of efficacy of RMM will lead to reduced chemical exposure of humans and wildlife. The LIFE APEX prioritisation schemes can be applied on any of the many tens of thousands of substances that fall under registered/approved chemical legislative frameworks such as REACH or BPR. The impacts are ambitious, in that LIFE APEX aims to change significantly the extent to which regulators make use of chemical monitoring data. The impacts are credible, in that (a) the proposed demonstrators, and the key elements to be developed to support and sustain regulatory take-up, are based on validated analytical methods; (b) the Beneficiaries have all the necessary expertise, experience, infrastructures and networks; (c) existing implementation guidelines make provision for incorporation of chemical monitoring data in hazard assessment; and (d) there is strong support for the proposal from ECHA, regulators, ESBs and NHMs.

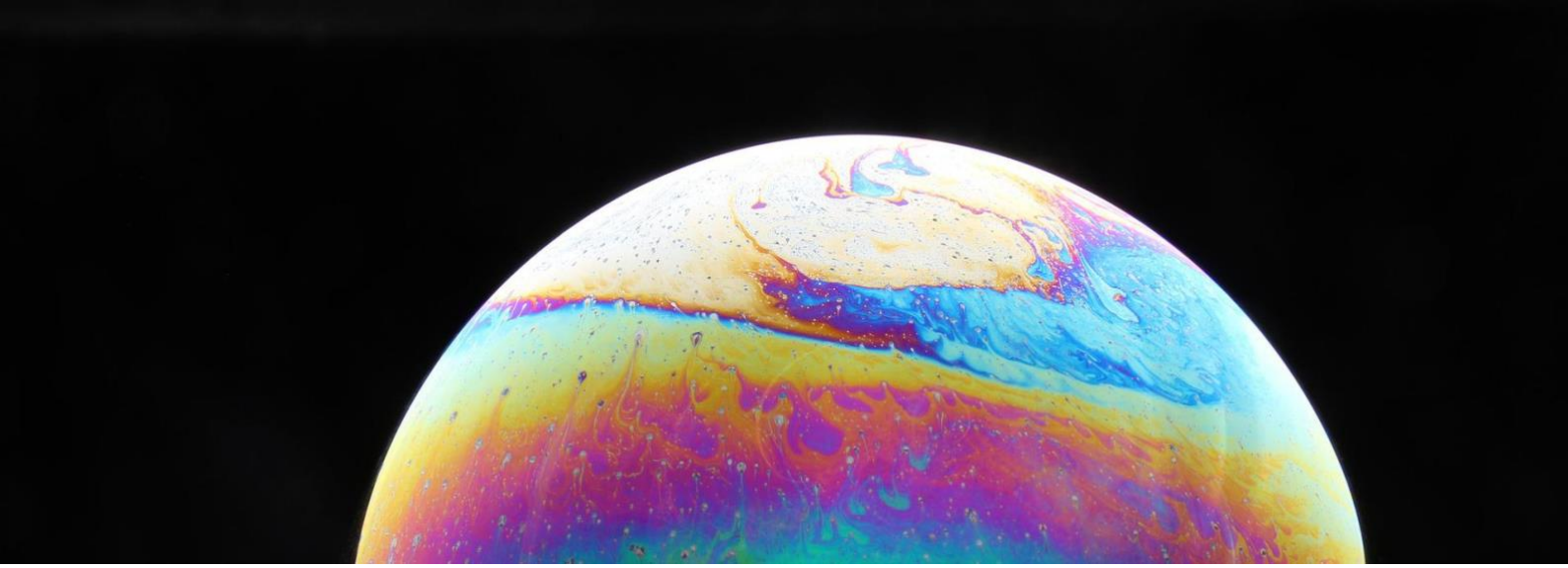
5. LONG-TERM SOCIO-ECONOMIC IMPACT

The detection of accumulating chemicals in food webs through to apex predators and their prey, the determination of predominant chemical mixtures in the environment, and the application of this information to the prioritisation on substances for hazard assessment, and to the hazard assessment itself, could be used for the earlier implementation of RMMs than would otherwise be the case. These measures may range from restrictions for certain uses of a substance, to a full ban. The socio-economic effects of such RMM are several. First, there is a socio-economic effect arising from the reduced exposure of humans and/or wildlife to harmful substances, in terms of less harm to human and/or wildlife health. Second, there is an economic impact of any restriction on the manufacturer of the substance and on the users of the substance.

Short of the implementation of RMM by law, the detection of substances and their transformation products in biota (Demonstrator 1) can provide an alarm signal to chemical producers and users. Even if substances do not show immediate toxic effects, their presence in apex predators signals potential for persistence and bioaccumulation. Responsible product stewardship warrants a life cycle responsibility for chemicals from synthesis to waste destruction. Demonstrator 1 can usefully inform such stewardship, raising awareness of risks of human and wildlife exposure and stimulating appropriate voluntary RMM by industry and down-stream users.

PBT assessment is by definition hazard-oriented. Continuous environmental exposure of humans and wildlife to anthropogenic chemicals is indeed a hazard, irrespective of toxicity. Ranking of chemicals in Demonstrator 2 will fuel discussion with market players on the load of chemicals to the environment, particularly from wastes. Demonstrator 2 will also provide guidance on assessment of B potential of substances and this will be of interest to industry and down-stream users.

Improved assessment of the effectiveness of RMMs (Demonstrator 3) might reveal that existing RMM are not working, or not working as optimally as they might. This might lead to changes in RMMs. As described above, the socio-economic effects of changing RMMs might include less harm to human and/or wildlife health, and an economic impact on the manufacturer and/or users of the substance. RMMs generally aim at reducing exposure at different stages of the life-cycle of a chemical, or in a matrix. This can significantly affect commercial viability. Consequently, RMMs (up to and including a full ban) undergo socio-economic analysis (SEA). While SEA methodology is by no means standardised and often very crude, tools developed by Demonstrator 3 might improve this methodology as they emphasize the need to take real environmental occurrence into account, rather than only generic exposure calculations and information provided by standardised laboratory tests.



There is at present no information on what might be the effects of co-occurring chemicals in biota samples. Demonstrator 4 will reveal the multitude of chemicals present in different species and statistically assess which 'appear frequently together'. This is aimed at triggering further (eco)toxicological research, including by industry, on the identified sets of chemicals and the additivity of their adverse effects. LIFE APEX will pursue synergies with other areas of EU chemicals legislative frameworks such as the Regulation on Plant Protection Products (PPPs) and Directive/Regulation on Human and Veterinary Medicinal Products, as well as environmental legislations such as the Water Framework Directive (WFD) and Marine Strategy Framework Directive (MSFD). This may lead to socio-economic effects in terms of reduced risk to human and wildlife health from these chemical substances in the environment.

It is not possible to quantify these socio-economic effects (e.g. in terms of reduced costs to human and/or wildlife health, or in terms of impact on jobs in and market revenues of chemical companies) because there are too many unknowns. We cannot predict how many chemicals our approach and methods will detect in AP&P within the project period, we cannot predict which predominant chemical mixtures they may reveal within the project period, and we cannot predict how these findings might influence hazard assessment and subsequent RMMs. Even less so can we predict the extent to which these approaches and methods may be taken up by regulators post project and thus the extent to which they might have a wide-ranging influence on the use of RMMs under REACH and BPR.

LIFE APEX may help improve the competitiveness of European chemicals companies to sustainable use of chemicals as proposed by the Chemicals Strategy on Sustainability within the European Green Deal by stimulating the development of substances that pose less risk to human and wildlife health. Improved access to higher quality chemical monitoring data may help to reduce costs for industry in compiling good quality substance dossiers.

LIFE APEX offers potential for benefit to regulators in terms of more efficient and therefore more cost-effective prioritisation of substances for hazard (PBT) assessment. This could represent a significant time-saving for officials working on this prioritisation, both within ECHA and NCAs, and thus a better use of public money.

The concrete societal benefits that could be achieved as a result of LIFE APEX implementation or its continuation relate to reduced exposure of humans and wildlife to contaminants, with consequent improvements in human and wildlife health. This could translate in to significant economic benefits in terms of reduced costs to national health systems and in terms of improved flow of ecosystem services (from healthier, better functioning ecosystems) and therefore of benefits and value from ecosystems. It was estimated that the annual burden and disease costs of exposure to endocrine disrupting chemicals in the EU to be €157 billion (1.23% of EU GDP). A 1% reduction in this burden, through reducing exposure to such chemicals in the environment, would thus deliver an economic benefit of €1.5bn per annum.

The Beneficiaries are all very well informed on issues relating to carbon footprint and implement policies and measures to reduce carbon footprint in their operations, including improving the energy performance of their buildings, the reduced use of non-renewable fuels, the use of energy-efficient office equipment, low-carbon modes of transport, virtual meetings and recycled paper, and generation of less waste. They provide training and facilities for staff to adhere to these policies and measures. Several of the LIFE APEX beneficiaries operate certified environmental management systems (e.g. EMAS or ISO14001) that aim to minimise carbon emissions.

6. EUROPEAN ADDED VALUE

Contribution to specific objectives of the E&RE priority area

LIFE APEX will contribute to:

- the specific objective "to develop, test and demonstrate policy or management approaches, best practices and solutions, including development and demonstration of innovative technologies, to environmental challenges, suitable for being replicated, transferred or mainstreamed by providing a between the environment and human health". This is archived by demonstrating management approaches and developing best practices for the use of chemical monitoring data, to better address the environmental challenge posed by chemicals; these approaches and best practices (protocols, guidance) will be suitable for replication, transfer and mainstreaming.
- the specific objective "to improve the knowledge base for the development, implementation, assessment, monitoring and evaluation of Union environmental policy and legislation, and for the assessment and monitoring of the factors, pressures and responses that impact on the environment within and outside the Union" – by improving knowledge for monitoring of EU chemicals legislation, and for assessment of chemical pressures on the environment.

Contribution to implementation of EU environmental legislation

LIFE APEX will contribute significantly to the implementation of REACH and BPR in particular by helping regulators:

- address the challenge of prioritising substances for hazard assessment – ECHA struggles with this, given the sheer number of substances (60000+). LIFE APEX demonstrates a novel approach to using AP&P chemical monitoring data (Demonstrators 1–2), offering a cost-effective way to facilitate prioritization.
- assess whether or not RMMs, such as restrictions on use of chemicals, are working or not, in terms of reducing exposure of humans and wildlife to harmful substances in the environment. LIFE APEX demonstrates a novel approach to use of AP&P chemical monitoring data (Demonstrator 3) by offering a cost-effective way to assess effectiveness of RMMs. As implementation of REACH and BPR proceeds, more and more substances will be subject to RMMs. If RMM are central to chemicals management, it is vital to know whether they are effective. This knowledge is all-the-more important given that RMMs imply costs to industry (e.g. reduced sales) and to society (e.g. more costly goods).

The use of AP&P chemical monitoring data proposed in LIFE APEX could also lead to development of chemicals regulation, for example adjusting the extent to which such data are required to be applied in hazard assessment, and/or adjusting RMM to make them more effective in reducing environmental exposure to hazardous substances.

Synergies with other EU policies, multi-purpose delivery mechanism and integration

LIFE APEX addresses several EU policies, while focussing on particularly on REACH and BPR. LIFE APEX supports the aims of REACH and BPR in protecting the environment and human health from harmful chemicals. LIFE APEX consequently contributes to the aims of other EU policies that incorporate protection of the environment and human health from harmful chemicals. This includes policies on the non-toxic environment incorporated within the Zero Pollution Ambition of European Green deal as well as the 7EAP and the Circular Economy and measures to secure the good ecological status of freshwaters under the Water Framework Directive (WFD), and of good environmental status of marine waters under the Marine Strategy Framework Directive (MSFD).

LIFE APEX will contribute to a wide range of other chemicals regulations addressing PPPs, human medicinal products, veterinary medicinal products, persistent organic pollutants, in that these can also benefit from better use of chemical monitoring data from AP&P for risk assessment, effectiveness evaluation and early warning. LIFE APEX may also contribute to the objectives of the EU Classification, Labelling and Packaging Regulation in that it will raise awareness of risks relating to certain chemicals that should be taken in to consideration in relation to classification, labelling and packaging.

LIFE APEX also contributes to the objectives of the EU Biodiversity Strategy of the Green Deal as well as Bird and Habitat Directives, which aim to protect species and habitats from threats including harmful chemicals. Most apex predators are protected under these directives, and better knowledge of the chemicals in apex predators will enable more effective conservation and restoration of these species, their habitats and other protected and unprotected species occurring in these habitats.

Theses synergies will be pursued through a multi-purpose delivery mechanism that is elaborated in Action D2 involving engagement of EU agencies and NCAs for REACH, BPR, other chemicals regulations, WFD, MSFD and the Nature Directives, together with Europe's ESBs, NHMs and other collections, eco-toxicologists, analytical chemists, and communications experts, to optimise use of chemical monitoring data from AP&P. By pursuing these synergies and integration, LIFE APEX will help deliver additional societal and economic benefits including: improved quality of marine and freshwaters; improved classification and labelling of chemicals; reduced environmental exposure to substances falling under the PPP, medicinal products and/or POPs regulations; and reduced exposure species to harmful substances in the environment.

Transnational approach

LIFE APEX involves a transnational approach, with beneficiaries from 6 countries with good geographical balance across Europe. Moreover, LIFE APEX will involve engagement of replication and transfer (R&T) partners from most other EU member states (MS). There is clear added value of this transnational approach because; (a) it brings together some of the best available expertise and top infrastructures (ESB, NHM, Research Collections) from around Europe; (b) it provides all the necessary infrastructures. This transnational approach is also important in helping to ensure that the approaches, methods, databases and protocols developed are European in nature, and secure Europe-wide ownership.

Green procurement

LIFE APEX applies best practice in green procurement policy, for example in relation to procurement of transport, consumables (e.g. stationery, laboratory equipment) and meeting venues (where these are external). LIFE APEX beneficiaries have a range of green procurement policies and guidelines. For example, UBA has published detailed Guidelines for Sustainable Organisation of Events and UKCEH are obligated by the Crown Commercial procurement system, which incorporates consideration of sustainability principles for suppliers and contractors. All procurement under LIFE APEX by beneficiaries that are public bodies will be in accordance with the latest EU Procurement Directive 2014/24/EU (as transposed into national procurement legislation). Procurement by private bodies will meet at least the same standards.

If you want to know more go to LIFEAPEX.EU

LIFEAPEX.EU

LIFEAPEX1

LIFE-APEX-PROJECT

European Commission