LIFE Project Number

LIFE17 ENV/SK/000355

Final report

Covering the project activities from 01/09/2018[1] to 31/08/2022

Reporting Date[2]

30/11/2022

LIFE PROJECT NAME or Acronym

LIFE APEX

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

Data Project

Project location:	DE, GR, IT, NL, SK, UK
Project start date:	01/09/2018
Project end date:	31/08/2022 **Extension date:** Not applicable
Total budget:	€ 3,353,413.00
EU contribution:	€ 2,012,047.00
(%) of eligible costs:	60

Data Beneficiary

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[1] Project start date

[2] Include the reporting date as foreseen in part C2 of Annex II of the Grant Agreement

This table comprises an essential part of the report and should be filled in before submission

Please note that the evaluation of your report may only commence if the package complies with all the elements in this receivability check. The evaluation will be stopped if any obligatory elements are missing.

Package completeness and correctness check	
Obligatory elements	**✓ or N/A**
Technical report	
The correct latest template for the type of project (e.g. traditional) has been followed and all sections have been filled in, in English *In electronic version only*	✓
Index of deliverables with short description annexed, in English *In electronic version only*	✓
Mid-term report: Deliverables due in the reporting period (from project start) annexed Final report: Deliverables not already submitted with the MTR annexed including the Layman's report and after-LIFE plan Deliverables in language(s) other than English include a summary in English *In electronic version only*	✓
Financial report	
The reporting period in the financial report (consolidated financial statement **and** financial statement of each Individual Beneficiary) is the same as in the technical report with the exception of any terminated beneficiary for which the end period should be the date of the termination	✓
Consolidated Financial Statement with all 5 forms duly filled in and signed and dated *Electronically Q-signed or if paper submission signed and dated originals* and in electronic version (pdfs of signed sheets + full Excel file)*	✓
Financial Statement(s) of the Coordinating Beneficiary, of each Associated Beneficiary and of each affiliate (if involved), with all forms duly filled in (signed and dated). The Financial Statement(s) of Beneficiaries with affiliate(s) include the total cost of each affiliate in 1 line per cost category *In electronic version (pdfs of signed sheets + full Excel files) + in the case of the Final report the overall summary forms of each beneficiary electronically Q-signed or if paper submission, signed and dated originals**	✓
Amounts, names and other data (e.g. bank account) are correct and consistent with the Grant Agreement / across the different forms (e.g. figures from the individual statements are the same as those reported in the consolidated statement)	✓
Mid-term report (for all projects except IPs): the threshold for the second pre-financing payment has been reached	**N/A**
Beneficiary's certificate for Durable Goods included (if required, i.e. beneficiaries claiming 100% cost for durable goods) *Electronically Q-signed or if paper submission signed and dated originals* and in electronic version (pdfs of signed sheets)*	**N/A**
Certificate on financial statements (if required, i.e. for beneficiaries with EU contribution ≥750,000 € in the budget) *Electronically Q-signed or if paper submission signed original and in electronic version (pdf)*	**N/A**
Other checks	
Additional information / clarifications and supporting documents requested in previous letters from the Agency (unless already submitted or not yet due) *In electronic version only*	✓
This table, page 2 of the Mid-term / Final report, is completed - each tick box is filled in *In electronic version only*	✓

**signature by a legal or statutory representative of the beneficiary / affiliate concerned*

Instructions:

Please refer to the General Conditions annexed to your grant agreement for the contractual requirements concerning a Mid-term/Final Report.

Both Mid-term and Final Reports shall report on progress from the project start-date. The Final Report must be submitted to the EASME no later than 3 months after the project end date.

Please follow the reporting instructions concerning your technical report, deliverables and financial report that are described in the document "Guidance on how to report on your LIFE 2014-2020 project", available on the LIFE website at: https://ec.europa.eu/easme/sites/easme-site/files/report-your-life-project-201909.pdf. Please check if you have the latest version of the guidance as it is regularly updated. Additional guidance concerning deliverables, including the layman's report and after-LIFE plan, are given at the end of this reporting template.

Regarding the length of your report, try to adhere to the suggested number of pages while providing all the required information as described in the guidance per section within this template.

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2. List of key-words and abbreviations

ABs	Associated Beneficiaries
APCI	Atmospheric pressure chemical ionisation
AP&P	Apex Predators and their Prey
BPR	Biocidal Products Regulation
CEH	Centre for Ecology & Hydrology
CETAF	Consortium of European Taxonomic Facilities
DCT	Data Collection Template
DSFP	NORMAN Digital Sample Freezing Platform
EC	European Commission
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EI	Environmental Institute
EOP	End of project
ERBFacility	European Raptor Biomonitoring Facility (COST Action 16224)
ESB	Environmental Specimen Bank
EU, EU MS	European Union, EU Member state
Fh-IME	Institute for Molecular Biology and Applied Ecology IME
GC	Gas chromatography
HBM4EU	European Human Biomonitoring Initiative
HR-MS	High resolution – mass spectrometry
ICPDR	International Commission for the Protection of the Danube River
IPCHEM	Information Platform for Chemical Monitoring
JRC	European Commission Joint Research Centre
LC	Liquid chromatography
MSCAs	Member State Competent Authorities
NATURALIS	Naturalis Biodiversity Center
NCI	Negative chemical ionisation
NGO	Non-governmental Organisation
NHM	Natural History Museum
MS	Mass spectrometry (or Member state)
NORMAN	Network of reference laboratories, research centres and related organisations for monitoring of emerging environmental substances; www.norman-network.net
NTS	Non-target Screening
OCPs	Organochlorine pesticides
OSPAR	Convention for the Protection of the Marine Environment of the North-East Atlantic
PBDEs	Polybrominated diphenyl ethers
PBT	Persistent, bioaccumulative, toxic (properties)
PCBs	Polychlorinated biphenyls
PCI	Positive chemical ionisation
PFAS	Perfluorinated alkyl sulphonates
POPs	Persistent Organic Pollutants
PPP	Plant Protection Products
PSC	Project Steering Committee
RAB	Regulatory Advisory Board
REACH	European Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals
R&T	Replication & Transfer

RI	Research Institute
RMM	Risk Management Measures
SEv	Substance evaluation
SOP	Standard Operational Procedure
UBA	"Umweltbundesamt" / German Federal Environment Agency
UKCEH	UK Centre for Ecology & Hydrology
UNIFI	"Università degli Studi di Firenze" / University of Florence
UoA	National and Kapodistrian University of Athens

3. Executive Summary

Chemical monitoring data from apex predators (e.g., raptors, otters, seals, marine mammals etc.) are of particular value; their position at the tops of food webs means they act as sentinels to reveal harmful substances, in terrestrial, freshwater and marine environments. When combined with data from selected prey (e.g., fish), **apex predator data can deliver useful quantitative information on persistence and bioaccumulation. LIFE APEX makes use of novel analytical methodologies that allow for screening of several thousands of chemical substances in each sample and prioritization of frequently occurring pollutants and their mixtures.** The project involves making better and more cost-effective use of chemical monitoring data from the large, valuable but under-used resource of environmental samples in Europe's Environmental Specimen Banks, Natural History Museums and other Research Collections. **LIFE APEX responds to needs of regulators for specific regulatory applications in relation to REACH and the Biocidal Products Regulation (BPR).**

The objectives of LIFE APEX were:

1. **To demonstrate four novel, regulatory applications of chemical monitoring data from apex predators and their prey (AP&P), specifically:**
   - to detect presence of chemical contaminants in the environment;
   - to facilitate selection of most relevant substances for further hazard assessment;
   - to assess impact and effectiveness of substance risk management measures (RMM);
   - to define predominant chemical mixtures in the environment.
2. **To support and sustain regulatory take-up of these applications, specifically:**
   - to assess relevant resources and capacities for replication and transfer and engage key partners;
   - to enhance quality assurance of sampling, processing, archiving and analysis of food web samples (and resulting data);
   - to enhance availability and access to relevant apex predator and prey samples and related chemical monitoring data and the comparability and interoperability of this data.
3. **To replicate and transfer LIFE APEX approaches and methods with partners across Europe.**
4. **To disseminate and communicate the LIFE APEX approaches and methods and in particular optimize uptake by regulators and industry.**

LIFE APEX demonstrates an approach to the use of chemical monitoring data from apex predators and their prey (AP&P) that is highly innovative. The novelty of the approach has several dimensions.

First, **LIFE APEX exploited recent technological advances in analytical methodologies in**

relation to wide-scope targeted analyses and non-target screening (NTS) to detect presence or absence of all compounds in an environmental sample. These methods have not before been applied EU-wide on biotic samples. There is currently only one EU-wide NTS database, that maintained by the NORMAN network (www.norman-network.net).

Second, **the project's approach sought, through four 'Demonstrators', to focus the use of AP&P chemical monitoring data of four specific applications for which such data have not before been applied for EU regulatory purposes, and which together offer considerable potential to enhance protection of human health and the environment.** These applications related to: (1) better identification of chemicals accumulating in the environment through terrestrial, freshwater and marine food webs; (2) better prioritisation of chemicals for hazard assessment and more informed hazard assessment; (3) more effective evaluation of risk mitigation and/or restriction measures under REACH and BPR; (4) and better determination of predominant chemical mixtures in the environment. Together, these four applications facilitated the assessment of risk at the 'front end' of the regulatory process, and also facilitated better understanding as to whether risk management, at the 'back end' of the regulatory process, really works in terms of reducing environmental concentrations of and exposures to hazardous chemicals.

Third, LIFE APEX involved a novel, complementary suite of three 'Key Elements', which supported and sustained the take-up of these novel applications. They were: **(1) the creation of a Europe-wide community bringing together Environmental Specimen Banks (ESBs) and National History Museums (NHMs) and analytical labs for the provision and analysis of AP&P samples for chemical regulatory monitoring applications; (2) the promotion of harmonised quality assurance (QA) for AP&P sampling, sample treatment and archiving across Europe; (3) the construction of an APEX KnowledgeBase to provide access to comparable and interoperable data on AP&P samples and related contaminant data from both targeted and NTS analyses.**

LIFE APEX will sensitise regulators to the advantages of making more and better use of monitoring data from biota, and in particular from apex predators, for risk assessments and evaluation of effectiveness of Risk Management Measures according to REACH legislation. It will also sensitize regulators to the value of ESB collections and to the complementary value of NHM collections in this regard.

Progress of project implementation

The LIFE APEX was progressing well, as initially planned in the project proposal. **The aims of the project were fulfilled**.

A community of **Replication & Transfer partners** holding the samples of AP&P across Europe has been established; a database **"APEX KnowledgeBase" was constructed** (more information is listed below) **to provide an access to comparable and interoperable data on AP&P samples** and related contaminant data from both targeted and NTS analyses, the database also contains a module **for storage of information on existing collections of AP&P samples** in Europe; **quality assurance protocols** for sample collection, storage, shipment across Europe and analysis of samples have been developed and tested (https://lifeapex.eu/documents/).

The LIFE APEX Database System was created. **Module 1 - LIFE APEX Sample Catalogue** of the LIFE APEX Database System (https://www.norman-network.com/apex/catalogue/) 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 on 3,253 targeted substances as of the end of October 2022** (https://www.norman-network.com/apex/lacod/). **Module 3 - Digital Sample Freezing Platform** (https://dsfp.norman-data.eu) is a database of mass chromatograms obtained by LC-HR-MS for retrospective screening of environmental samples. **HRMS chromatograms of all 198 analysed samples of Tier 1 (67), Tier 2 (68) and Tier 3 (63)** were

uploaded to **NORMAN Digital Sample Freezing Platform** and enabled suspect screening of environmentally relevant pollutants from the NORMAN Substance Database (SusDat; https://www.norman-network.com/nds/susdat/; 65,691 substances) in all raw chromatograms. For more details on the procedure, see https://doi.org/10.1016/j.trac.2019.04.008. The detected suspected substances were subjected to prioritization to reveal the most hazardous substances detected in the top predators and their prey.

The LIFE APEX database is of increasing interest for external partners who are willing to share their biota analyses data in a harmonised format (e.g., **OSPAR (North-East Atlantic, CONNECT project), ICPDR (Danube River Basin; Joint Danube Survey 4), HELCOM (Baltic Sea, Pre-EMPT and UBA-HELCOM projects), Black Sea (EU/UNDP EMBLAS projects) and Antarctica (NORMAN)**). The LIFE APEX Database System is being continuously updated. A **prioritisation module** (https://norman-data.eu/lifeapex2/#!/customized) has been developed in line with the **NORMAN Prioritisation Framework** and thoroughly tested. The module allows for ranking of pollutants determined in AP&P samples using their **risk** (exceeding of toxicity threshold values), **hazard** (persistence, bioaccumulation, toxicity - PBT) and **exposure** (frequency of appearance, annual production tonnage, widespread of use) assessments in various scenarios. The prioritisation of Tier 1 & 2 samples has been performed separately for different matrices (marine mammals, otters, raptors) and the top-ranking substances were subjected to PBT assessments at UBA. Model-based PBT predictions were generated by UBA for ca. 66,000 substances using JANUS Tool (https://www.vegahub.eu/portfolio-item/janus/).

Three applications were developed in the context of LIFE APEX to visualize results of Tier 1 & 2 analyses. The application https://norman-data.eu/LIFE_APEX2 shows spatial distribution of chemical contaminants determined by wide-scope target screening in the Tier 1 samples. The application https://norman-data.eu/LIFE_APEX_Tier2 allows visualizing variations in concentrations of contaminants detected by suspect screening in the time-series samples of Tier 2 (2000–2019). A third application (https://norman-data.eu/LIFE_APEX_Mixtures) was developed to detect the predominant mixtures in AP&P samples.

All applications will be integrated in the LIFE APEX Database System after the publication of the findings, to be easily accessible by the broader audience. The applications are being used at the in-depth analysis of the results, mainly to reveal pollution patterns.

The project's identity has been firmly established with its website **https://lifeapex.eu/** and **seven Newsletters** have been published to inform about the project progress (https://lifeapex.eu/dissemination/). **Several peer reviewed papers and numerous presentations** of project outputs have already been disseminated at various top **European level conferences**, the list of publications, posters and abstracts "LIFE APEX project presented at international conferences" can be found here: https://lifeapex.eu/publications/. Other submitted publications await official publication. We provided regular information on the progress of LIFE APEX within **NORMAN network** (https://www.norman-network.net/), **OSPAR** (https://www.ospar.org/), **HELCOM** (https://helcom.fi/) **Regional Sea Conventions** at their various expert group meetings.

The LIFE APEX approach is currently being considered by both the **OSPAR Commission (**https://www.ospar.org/) and **HELCOM** (https://helcom.fi/) **Commissions** to gather a critical mass of data for an update of the North Sea and Baltic Sea specific list of contaminants. LIFE APEX was also presented by Jaroslav Slobodnik (EI) on **THE EIONET AD-HOC EXPERT GROUP ON CHEMICALS meeting: Chemicals strategy for sustainability (26–27 January 2021)**, organised by **German Environment Agency (UBA)** and **European Environment Agency (EEA)**.

There was an existing collaboration between LIFE APEX and **European Raptor Biomonitoring Facility COST Action (CA16224)** which was mentioned in the ERBFacility Newsletter from April 2021 (to be found in the frame of Highlights on LIFE APEX website). LIFE APEX was presented at **ERBFacility WG3 virtual meeting: The Role of Collections for Contaminant Monitoring in**

Raptors across Europe – State of Play and Next Steps on 11–12 February 2021. The meeting was set up to inform and inspire natural science collections to engage in pan-European contaminant monitoring. The aims and objectives of LIFE APEX project were presented at **Tox Forum meeting at NiPH, Norway on 12 March 2021** as well as at the **Meeting of the Hazardous Substances and Eutrophication Committee (HASEC)** / Videoconference on 22–26 March 2021, organised by **OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic**.

We also cooperate with the EC on the update of the list of contaminants in Descriptors 8 and 9 of the **Marine Strategy Framework Directive (MSFD)**, sharing data with the **EC IPCHEM** (https://ipchem.jrc.ec.europa.eu/), and sharing information with **ECHA** in support of the **Substance Evaluation scheme under REACH legislation**. LIFE APEX project was also mentioned in **Technical report about IPCHEM by the Joint Research Centre (JRC)**, the European Commission's science and knowledge service (https://ipchem.jrc.ec.europa.eu/documents/JRC123154_ipchem_2020.pdf).

All of the above was well appreciated by the **project's Regulatory Advisory Board** (https://lifeapex.eu/rab-members/) who were encouraging the project to deliver the risk assessment methodologies and supporting results as soon as possible in **support of European chemicals management policies**. **Two LIFE APEX policy briefs were published** (cf. Technical part / Deliverable D.1.4, Annex 1 and Annex 2).

No significant difficulties preventing implementation have been encountered and the project was progressing as planned. A detailed summary of achievements is presented below (cf. Technical part).

4. 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. $8,500 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 people. 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 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.

Expected results (outputs and quantified achievements):

Direct results from LIFE APEX actions are:

- Key Element 1: Inventory of ESBs, NHMs and other collections involved in collecting AP&P samples.
- Key Element 2: Review and guidance documents on QA criteria, measures and protocols for sampling, processing and archiving of AP&P samples, analysis of chemical contaminants in AP&P, and assessing quality of AP&P contaminant data.
- Key Element 3: A European database, well populated with data from across Europe, with three modules: (a) samples module with samples data from ESBs/NHMs; (b) target analyses data module; (c) non-target screening data module [(b and (c) together containing >1 data million entries].
- Demonstrators 1: List of chemicals in AP&P samples.
- Demonstrators 1 & 2: List of top 300 contaminants in AP&P samples, guidance document for assessment of PBT properties of contaminants in AP&P samples.
- Demonstrator 3: Guidelines and framework for monitoring terrestrial pollutants to assess success of chemicals risk management measures.
- Demonstrator 4: List of predominant mixtures in AP&P samples.
- All Demonstrators: Protocols for regulatory applications, take-up by ECHA and Member State Competent Authorities.
- Project website, video, peer-reviewed publications of key methods and applications.
- Project technical and financial reports, performance reports (in relation to performance indicators).
- Layman's report.
- After-LIFE Plan.

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 **longer-term (post-project) 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 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 ESBs, 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.**

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 (60,000+). LIFE APEX demonstrates a novel approach to using AP&P chemical monitoring data (Demonstrators 1–2), offering a cost-effective way to facilitate prioritisation;
- **assess whether or not risk management measures (RMM)**, such as restrictions on use of chemicals, are working on 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) offering a cost-effective way to assess effectiveness of RMM. As implementation of REACH and BPR proceeds, more and more substances will be subject to RMM. If RMM are central to chemicals management, it is vital to know whether they work of not. This knowledge is all-the-more important given that RMM 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.

LIFE APEX will also contribute to a wide range of other chemicals regulations addressing plant protection products (PPP), 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 **Birds and Habitats 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.

5. Administrative part

The Project Coordinator, Jaroslav Slobodnik (EI) focused on overall project coordination between Beneficiaries and across Actions. **The Project Manager, Natalia Glowacka (EI)** provided day-to-day project management and administrative support to the Coordinator. **The Financial Manager, Olha Khymych (EI/external)** managed all financial matters. The provision for an **External Assistant, Guy Duke (EI/external)** for 'Reporting and Assessment' was for support to the EI Project Coordinator for reporting to the European Commission and for oversight of scientific, technical, financial and administrative risks to the project. The Project Coordinator retained supervisory responsibility and sign-off for reports to the EC.

The top decision-making body was the **Project Steering Committee (PSC)** (cf. Annex 3 submitted with **the Mid-term report on 27/02/2020**). Minutes of the (3) PSC Meetings are a part of this report (cf. 9. List of annexes: Annex 10, Annex 11, Annex 12). Minutes of the 1st and 2nd PSC Meeting

were provided with the Mid-term report. **Members of PSC included the Project Coordinator (PSC Chair) and Project Manager (both EI), a representative of each Associated Beneficiary (AB):**

- **Gabriele Treu (UBA) – replaced by Jan Koschorreck (UBA)**
- **Richard Shore (CEH) – replaced by Lee Walker (UKCEH)**
- **Nikolaos Thomaidis (UoA)**
- **Rene Dekker (Naturalis)**
- **Alessandra Cincinelli (UNIFI)**
- **Heinz Ruedel (Fh-IME) – cancelled due to withdrawal of Fh-IME from LIFE APEX consortium**

The PSC met face-to-face or virtually. Decisions were taken by consensus or, when necessary, by vote, with one vote per Beneficiary (when the vote was split, the Chair had the casting vote). **The PSC had the following standing Sub-Groups** (cf. Annex 7 submitted with **the Mid-term report on 27/02/2020**), reporting to the PSC, each with 4-5 members appointed by the PSC. Each met quarterly, in advance of the PSC (face-to-face or virtual):

- **Replication and Transfer (R&T) Sub-Group**: responsible for coordination of R&T activities across the Implementation Actions. Total 4 members chaired by UBA.

- **Dissemination and Communication (D&C) Sub-Group**: responsible for development, implementation and updating of the Dissemination and Communication Strategy, and advising on Actions D1 and D2. Total 6 members, chaired by EI.

- **Audit and Risk (A&R) Sub-Group**: responsible for advising on risk and on audit of project finances. The Sub-Group regularly reviewed and updated a significant risk register, specifying the nature of the risks, their risk rating, risk mitigation measures, and quarterly update on action taken. The Sub-Group also reviewed project financial reports and audits from the Project Management Group (PMG) and recommended their approval to the PSC. Total 4 members, chaired by external Reporting & Risk Expert.

The **LIFE APEX Organigram** is presented below (Figure 1).

Monitoring of project implementation (technical part)

Issues involved with the implementation of the project were discussed with assigned **NEEMO Monitor Mr. Daniel Svoboda, MSc.**

Brief LIFE APEX project reports were submitted to **NEEMO Monitor Mr. Daniel Svoboda, MSc. upon request** as follows:

- brief project report - covering the project activities from 30/11/2019 to 31/12/2020 was submitted on 18 January 2021;
- brief project report - covering project activities from 01/04/2021 to 15/12/2021 was submitted on 17 December 2021.

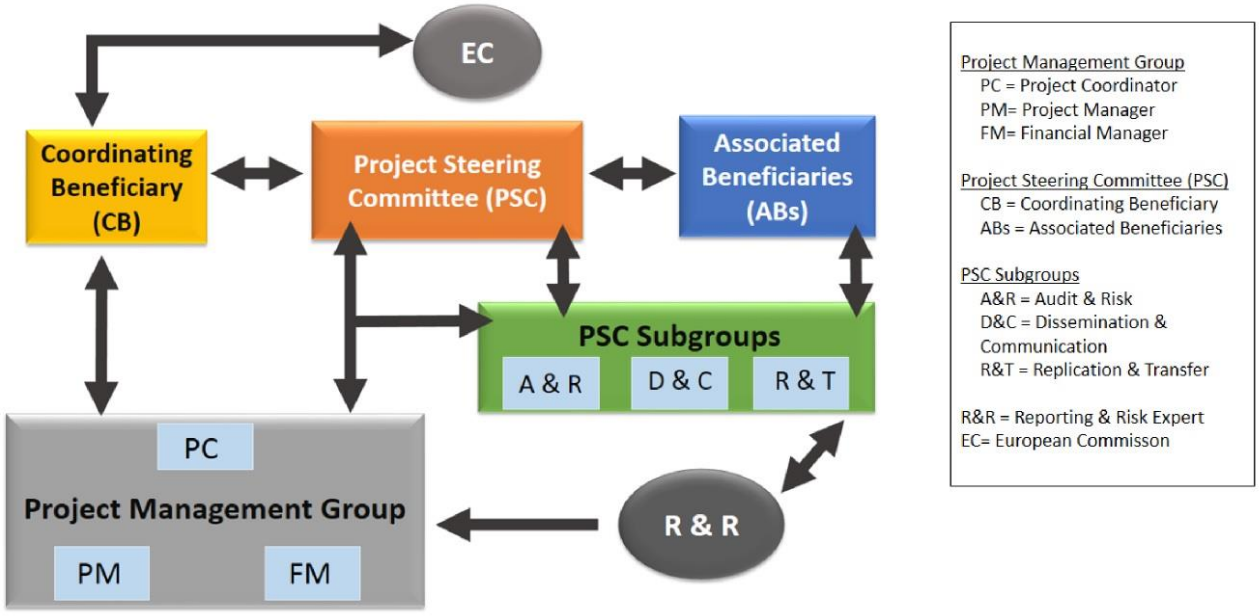
Mid-term Monitoring Report was submitted on 27/02/2020 and **Progress Monitoring Report was submitted on 25/06/2021** to the European Commission.
The **Amendment to the Grant Agreement LIFE17 ENV/SK/000355** covering administrative modification, partnership modification and financial structure modification (budget shifts between the partners) was submitted to European Commission on 15 March 2022, with the entry into force on 25 May 2022.

Responses to EASME/CINEA Letters:

- The response to the letter from the European Commission (Ref.: **Ares(2019)2684813 – 17/04/2019**) after 1st project monitoring visit was submitted with the Mid-term report on 27/02/2020 – cf. see "Annex 8".
- The response to the letter from the European Commission (Ref.: **Ares(2020)2105137 - 17/04/2020**) after the next monitoring visit was submitted to the NEEMO Monitor Mr. Daniel Svoboda, MSc. on 07/01/2021.
- The response to the letter from the European Commission (Ref.: **CINEA D.2/MM/D(2021) 4882986/Ares(2021)4326705 - 02/07/2021**) is provided with this report (Annex 9).
- The response to the letter from the European Commission (Ref.: **CINEA D.2/MM/D(2022) 5889844/Ares(2022)5356326 – 25/07/2022**) is provided with this report (Annex 8).

There were two changes in the LIFE APEX consortium. Associated beneficiary **UK Centre for Ecology & Hydrology (CEH)** that previously operated as part of the Natural Environment Research Council had changed legal name and legal status from non-departmental public body to 'not for profit charity' starting from 1 December 2019. The Associated Beneficiary **Institute for Molecular Biology and Applied Ecology IME (Fraunhofer IME)** left the LIFE APEX consortium in November 2019. Fraunhofer IME had committed itself to support LIFE APEX consortium with all tasks originally intended for their institution, on their own expenses, without the requirement for financial contribution from the project consortium. Their duties were taken over by Environmental Institute (EI) with the support of Fraunhofer IME. The **Amendment to the Grant Agreement LIFE17 ENV/SK/000355** covering administrative modification, partnership modification and financial structure modification (budget shifts between the partners) was submitted to European Commission on 15 March 2022, with the entry into force on 25 May 2022.

Figure 1. The LIFE APEX Organigram.



6. Technical part

6.1. Technical progress, per Action

ACTION B1: KEY ELEMENT 1:
Engaging key Replication and Transfer (R&T) Partners, assessing R&T Partners' resources and capacities for AP&P chemicals monitoring and developing an R&T Plan

Foreseen start date:	**Q3 2018 (1 September 2018)**
Actual start date:	**Q3 2018 (1 September 2018)**
Foreseen end date:	**Q3 2022 (31 August 2022)**
Actual end date:	**Q3 2022 (31 August 2022)**

B1.1 Complete list of potential R&T partners (Lead Naturalis, Support UBA, EI) Status: Completed

We have built on our existing networks of contacts. UBA is one of the biggest ESBs worldwide and has a clear overview of European ESBs, having organised several ESB conferences and hosting the International ESB (IESB) Group. Naturalis is one of the biggest NHMs worldwide and has an equally clear overview of European NHMs, not least as a member of the CETAF Executive Committee (Consortium of European Taxonomic Facilities; 58 major European collections). Our labs (EI, Fh-IME/former Associated Beneficiary, UoA, UNIFI, UKCEH/former CEH) are well connected to other relevant labs across Europe. A comprehensive list of potential R&T partners (collections, labs) and their potential areas of interest in relation to LIFE APEX objectives and proposed R&T activities has been drawn up (**see document submitted with the Mid-term report on 27/02/2020** - "Deliverable B.1.3"; cf. also sub-action B1.4 below).

B1.2 Contact potential R&T partners to gauge interest and ability to engage (Lead Naturalis, Support UBA, EI) Status: Completed

We have contacted all potential R&T partners with a description of LIFE APEX objectives and actions, focussing on R&T activities, and sought their interest and ability to engage. Many such partners had already indicated, at LIFE APEX proposal stage, their willingness to engage in relation to a range of R&T activities. We have built on these initial expressions of support, reaching out to other institutions, including through IESB and CETAF (CETAF members often coordinate or participate in national/regional networks of collections, providing nodes through which LIFE APEX can connect with and engage members of these networks).

B1.3 Kick-start R&T Partner engagement, develop R&T Plan (Workshop) (Lead Naturalis, Support UBA, EI) Status: Completed

We prepared and convened a 3-days LIFE APEX Workshop on engagement of replication and transfer (R&T) partners and a Winter School on ESB's operation on 21-23 January 2019 (Bratislava, Slovakia) (**see document submitted with the Mid-term report on 27/02/2020 –** "Deliverable B.1.1, Annex 2") with 19 representatives from 16 most-interested R&T Partners/Institutions (**see document submitted with the Mid-term report on 27/02/2020 –** "Deliverable B.1.1, Annex 1"), to kick-start R&T Partner engagement. The workshop focused on proposed R&T activities under Actions B1–B6, sought R&T Partner advice on these and develop an R&T Plan (**see documents submitted with the Mid-term report on 27/02/2020 – "**Deliverable B.1.2/B.1.4, Annex 1") for their engagement. The updated and final versions of R&T plan are provided with this report (Deliverable B.1.5, Annex 1 / Deliverable B.1.6, Annex 1).

B1.4 Assess R&T Partners' resources and capacities for AP&P chemicals monitoring (Lead Naturalis, Support UBA, EI) Status: Completed

ESBs and NHMs were asked to fill in an on-line questionnaire on resources and capacities. In October 2018, a questionnaire was sent to 178 institutions in 37 countries from an on-line list of 305 natural history bird collections.[3] Only institutions holding scientific bird collections of relevant size (>5,000 specimens) were included. The questionnaire was produced, distributed and analysed through and in close cooperation with COST Action 16224 (European Raptor Biomonitoring Facility) under the supervision of Naturalis, who coordinated Action B.1. Responses were received from 116 institutions (65%) from which we gathered actual contact information, updates on their raptor (= Apex predator) holdings, and information about current research, including chemical management studies. All 116 respondents were potential R&T partners, having been informed about LIFE APEX plans and having collections and/or fresh samples available for contaminant analysis (Note: target was 75 R&T partners). A map with cities with NHMs/ESBs/RIs from which we received a response was provided in "Deliverable B.1.3, Annex 1" (**see document submitted with the Mid-term report on 27/02/2020)**. A selection of respondents, especially national collections with holdings of >100,000 samples, was invited to and participated in a workshop in Bratislava in January 2019 (sub-action B.1.3, see above). The responses showed that both large national as well as smaller regional NHMs have significant numbers of contemporary raptor specimens and are interested to participate as providers of such samples for chemical monitoring to and with ESBs and RIs (Ramello *et al.* 2022). The results have been used to select appropriate R&T partners and were published in a peer reviewed journal: Ramello, G., Duke, G., Dekker, R.W.R.J. van der Mije, S., Movalli, P., A novel survey of raptor collections in Europe and their potential to provide samples for pan-European contaminant monitoring, *Environmental Science and Pollution Research*, Volume 29, 2022 (https://link.springer.com/article/10.1007/s11356-021-16984-8).

The bonus for NHMs is additional use and information to their samples, samples which up to now are frequently discarded, and possible co-authorship in publications resulting from their samples. It will give NHMs more visibility in, what is for them, a new scientific discipline: through LIFE APEX they will contribute and participate in environmental (contaminant) studies with a high social impact, putting them on the map for other than biodiversity (taxonomy, ecology, etc.) studies only.

A LIFE APEX Collection Metadata Template (**see document submitted with the Mid-term report on 27/02/2020 –** "Deliverable B.1.3, Annex 2") (part of Action B.3.1) was approved by the LIFE APEX team in October 2019 and has been sent to selected R&T partners (**see document submitted with the Mid-term report on 27/02/2020 –** "Deliverable B.1.1, Annex 1") who attended the LIFE APEX Workshop in Bratislava (B1.3 above). A separate questionnaire to gather data on resources and capacities of analytical labs across Europe has been distributed in Q3 and reported in Q4 by Action B.2 (Annex 1).

B1.5 On-going support to R&T Partner engagement (Lead: Naturalis. Support: UBA, EI) Status: Completed

R&T Partner engagement was largely promoted through specific activities under the R&T Plan (the updated versions of the R&T Plan are provided with this report (Deliverable B.1.5, Annex 1 / Deliverable B.1.6, Annex 1)), building on R&T activities proposed under the other Implementation Actions (B2-B6). This sub-action provided general on-going support to R&T Partner engagement including: (a) regular communications with key R&T Partners including feedback on activities and outputs; (b) regular promotion of LIFE Apex through IESB and CETAF and their national/regional networks/nodes; (c) monitoring and updating the R&T Plan as appropriate (led by an R&T Sub-group reporting to the PSC – see Action E1); (d) invitation of R&T Partners to other project meetings, including Meeting 8 / Final Conference. The agenda of the Final Conference is provided with this report (Annex 2).

[3] https://www.nhm.ac.uk/research-curation/scientific-resources/collections/zoological-collections/ebeac/database.html

The planned and predicted outputs of Action B.1 were proceeding according to the LIFE APEX plan. No deviations have been identified. This Action was a Key Element for R&T, scale-up and sustainability of the project approach. ESBs, NHMs and other collections and analytical labs have an important role to play in the generation and use of AP&P chemicals monitoring data, through the provision of relevant AP&P samples and their analysis. Collections could also provide important contextual data (e.g., food web data) to support the interpretation of chemical monitoring data. ESBs were specifically oriented to the collection, treatment and storage of biotic samples for chemicals monitoring. ESBs across Europe hold a substantial number of AP&P samples that LIFE APEX could make use of. While NHMs are better known for their large historical collections, most also receive contemporary AP&P specimens and store these in their freezers. These contemporary specimens are often not recorded in publicly available databases but represent a substantial potential resource for AP&P chemical monitoring. LIFE APEX developed an inventory of these specimens with a view to making them visible and available for chemical monitoring (see Action B3).

LIFE APEX was collaborating with the COST Action "European Raptor Biomonitoring Facility (ERBFacility)" which was assisting in bringing together raptor collections in Europe for contaminant research and monitoring in relation to chemicals regulation. The project also maintains close links with the NORMAN network, using its latest lists of (65,000+) substances with accompanying information (https://www.norman-network.com/nds/susdat/) for screening biota samples. The project's approach was also shared with the OSPAR MIME Expert Group which is using LIFE APEX protocols to obtain data for prioritisation of new OSPAR priority contaminants. Similarly, HELCOM Expert Group on Hazardous Substances used the protocols for prioritisation of the Baltic Sea specific contaminants. The LIFE APEX monitoring workflow has been applied to biota samples obtained within the Joint Danube Survey 4 organised by the International Commission for the Protection of the Danube (ICPDR; 14 European countries; http://www.danubesurvey.org/jds4/about).

The potential for continuing activity after end of project are foreseen mainly in the wide engagement of ESBs, NHMs and other collections and labs in generating high quality contaminant data from AP&P samples.

Apex predators are not typically systematically sampled by ESBs, being species that are usually protected by law, for which systematic sampling (e.g., shooting or invasive sampling of tissues) is rightly not an option. However, large numbers of apex predator specimens found dead by the general public (e.g., road kills, strandings, etc.) reach ESBs and NHMs every year. Those arriving at multi-species ESBs (e.g., German, Swedish ESBs) or at single taxa specimen banks (e.g., UKCEH Predatory Bird Monitoring Scheme, https://pbms.ceh.ac.uk) are treated and stored following protocols with future chemical analysis in mind. Those arriving at NHMs are often stored in freezers but, if used at all, tend to be converted to skins and/or skeletons, while soft tissues are often discarded with little thought of their value for chemical monitoring. In this sense, ESBs and NHMs are separate worlds. Nonetheless, NHMs across Europe have thousands of AP&P specimens stored in their freezers and offer potential to accumulate many more. LIFE APEX bridged the gap between ESBs and NHMs in order that the valuable resource of NHM samples complements those of ESBs to support the generation and use of AP&P chemical monitoring data for regulatory applications. NHMs are permitted to possess and distribute species or parts of legally protected species under CITES (Convention on International Trade in Endangered Species of Wild Fauna and Flora). This will facilitate the necessary exchange of tissues between institutions and countries.

ACTION B2: KEY ELEMENT 2:
Reviewing and harmonizing quality assurance (QA) for AP&P sampling, sample processing and archiving and for their chemical analysis

Foreseen start date:	**Q1 2019 (1 January 2019)**
Actual start date:	**Q1 2019 (1 January 2019)**
Foreseen end date:	**Q3 2021 (30 September 2021)**
Actual end date:	**Q3 2021 (30 September 2021)**

SUB-ACTIONS

B2.1 Review existing QA for sampling, processing and archiving of AP&P samples (Lead Fh-IME/former Associated Beneficiary, Support UBA, Naturalis) Status: Completed

This action has involved gathering and reviewing QA criteria, measures and protocols from ESBs and NHMs (both LIFE APEX beneficiaries and R&T partners). UBA, housing one of the foremost ESBs worldwide, has leading expertise in ESB QA criteria, measures and protocols for sampling, transport, processing and archiving of samples at cryogenic temperatures summarised in UBA's Standard Operating Procedures (SOP). Additionally, UBA gathered additional expertise from European ESBs via IESB. In addition to UBA's SOP, the Manuals of the Swedish NHM and Standards for Contaminants in Wildlife Tissue of the US NIST have also been reviewed. Naturalis gathered input from NHMs via CETAF. The project labs (EI, Fh-IME/former Associated Beneficiary, UoA, UNIFI, UKCEH/former CEH) have between them leading European expertise in relevant targeted analyses, wide-scope targeted analyses and NTS analyses, and have provided input on related QA issues. Using the above inputs, indicators for assessing the quality of samples and their suitability for environmental monitoring studies have been developed (**see document submitted with the Mid-term report on 27/02/2020 –** "Deliverable B.2.1, Annex 1") and are available here: https://lifeapex.eu/documents/. Standards have been elaborated for quality control (QC) measures related to sampling, processing and archiving. Based on indicators and parameters identified, work under B2.1 has also established criteria/metadata to be used in the Data Collection Template (DCT) developed in Action B3.1 (sub-action B.2.1). See Deliverable B.2.2, Deliverable B.2.3: Annex 1 – Annex 5.

B2.2 Winter School: ESB archive build-up, organization, technical operation and sample handling (Lead Fh-IME/former Associated Beneficiary) Status: Completed

A 3-days workshop was organised in Bratislava, Slovakia on 21-23 January 2019 with 19 representatives of 16 selected R&T Partners. One day of the workshop was devoted to a Winter School on ESB's operation (**see document submitted with the Mid-term report on 27/02/2020 -** "Deliverable B.1.1, Annex 2") focused on sample archive build-up, organization, technical operation and sample handling tasks under cryogenic conditions.

B2.3 Develop guidance for AP&P sampling, processing and archiving (Lead UBA) Status: Completed

Guidance documents for AP&P sample selection, processing, labelling and shipping have been developed (**see document submitted with the Mid-term report on 27/02/2020 –** "Deliverable B.2.1, Annex 2, Annex 3"). LIFE APEX guidance documents are also available here: https://lifeapex.eu/documents/. This built on the B2.1 review (see above). Standards were set for monitoring of AP&P samples in relation to a variety of objectives, and taking into account the differing infrastructures, resources and primary purposes of ESBs and NHMs. The main aim of these guidelines was to support better use of ESB and NHM samples for chemical monitoring in future. The guidelines were developed in consultation with relevant R&T Partners identified in Action B1 to enhance ownership and take-up. See Deliverable B.2.2, Deliverable B.2.3: Annex 1 – Annex 3.

B2.4 Develop guidance on chemical analysis of AP&P samples (Lead EI) Status: Completed

Guidance on chemical analysis of AP&P samples (available here: https://lifeapex.eu/documents/) has been developed (**see document submitted with the Mid-term report on 27/02/2020 –** "Deliverable B.2.1, Annex 4"). It describes the workflow covering both targeted and NTS analyses, taking into account state-of-the-art practices in Europe and harvesting know-how from the NORMAN network (a key R&T Partner). The guidance was tested during the Tier 1 samples analysis and further improved throughout the project duration. See Deliverable B.2.2, Annex 4 and Deliverable B.2.3, Annex 4.

B2.5 Develop guidance on assessing quality of AP&P chemical monitoring data (Lead UBA, Support EI, Naturalis and Fh-IME/former Associated Beneficiary) Status: Completed

This action built on the B2.1 review. In the first reporting period, draft criteria have been developed to assess the quality of the samples and their suitability for the specific monitoring aims, e.g. temporal trend assessment or screening exercises. This guidance will increase the regulatory update of data from AP&P samples to support chemicals legislations. We consulted the draft guidance with regulatory users and industry and the final guidance with the title: *"Making use of apex predator sample collections: an integrated workflow for quality assured sample processing, analysis and digital sample freezing of archived samples"* was submitted for publication in a peer-reviewed journal (*Chemosphere*). The article was published on 30 September 2022 and is available here: https://www.sciencedirect.com/science/article/pii/S004565352203096X?via%3Dihub.

The guidance on assessing quality of AP&P chemical monitoring data is submitted together with this report (See Deliverable B.2.2, Annex 5 and Deliverable B.2.3, Annex 5).

The planned and predicted outputs of Action B.2 proceeded according to the LIFE APEX plan. No deviations have been identified. Under this Action, standards for QC measures related to sampling, processing and archiving have been elaborated. Based on indicators and parameters identified, B2.1 has established the criteria to be used in the DCT developed in Action B3.1. A high level of QA is fundamental to ensure interoperability of chemical monitoring data and reliability of data for regulatory use. Without appropriate QA, it will not be possible to scale up and sustain regulatory uptake of AP&P chemical monitoring data from the rich resource of AP&P samples in ESBs, NHMs and other collections. There is at present a lack of widely accepted QA schemes for chemical monitoring in AP&P, including all steps of sampling, processing, archiving and analysis; protocols vary between institutions.

In general, QA for sampling, processing and archiving of samples for chemical analysis is more developed for ESBs than for NHMs, reflecting the differing primary purposes of these institutions. Work under this Action has specified a minimum QA for NHMs, building on ESBs expertise, to meet the needs of interoperability and reliability. It has built on previous relevant work on harmonisation of protocols, including work done under European Science Foundation's Research Networking Programme EURAPMON (2010-15) on raptor sampling and ensured synergy with the EU COST Action ERBFacility (2017-2021). Replication and Transfer (R&T) activities within the sub-actions have extended this Action to key R&T Partners across Europe.

An interlaboratory trial on suspect screening in biota was being carried out by the NORMAN network in 2019–2020, addressing application of novel analytical methodologies to compare sample preparation techniques for suspect screening workflows. This Action was a Key Element for R&T, scale-up and sustainability of the project approach. The developed review and guidance documents on QA measures and protocols for (1) sampling, processing and archiving of AP&P samples, (2) analysis of chemical contaminants in AP&P, and (3) assessing quality of AP&P contaminant data, will set up a framework for future European regulatory monitoring network of AP&P samples (available here: https://lifeapex.eu/documents/).

ACTION B3: KEY ELEMENT 3:
Enhancing access to relevant AP&P samples and related contaminant data, and enhancing compatibility and interoperability of data, through an APEX Knowledge Base

Foreseen start date:	**Q3 2018 (1 September 2018)**
Actual start date:	**Q3 2018 (1 September 2018)**
Foreseen end date:	**Q4 2021 (31 December 2021)**
Actual end date:	**Q4 2021 (31 December 2021)**

SUB-ACTIONS

B3.1 Construction and population of Module 1: APEX Samples Database (Lead UKCEH/former CEH (DCT design), EI (database construction), Support: Fh-IME/former Associated Beneficiary, UBA, Naturalis) Status: Completed

APEX Samples Database stores data on AP&P samples in ESBs, NHMs and other collections. It has capacity to store data on all available AP&P samples in Europe. It is a meta-database, allowing users to search which samples, from which locations and for which time periods are available in which collections, and whether there is any contaminant data (stored in Module 2) related to these samples. The current state of the database structure can be seen at https://www.norman-network.com/apex/catalogue/ (the login details are: Login: lifeapex, Password: lifeapex). The Module 1 contains 104 entries, with the data on samples from the NHMs and ESBs in Europe.

During the development of the database, UKCEH (former CEH) designed an Excel-based DCT (**see document submitted with the Mid-term report on 27/02/2020** – "Deliverable B.3.1, Annex 1") based on a similar DCT developed by UKCEH for the UK Virtual Specimen Bank, with information fields 'ready-for-upload-into-database'. The updated and final version of the DCT is submitted with this report (Annex 3).

Fh-IME (former AB) commented on the draft DCT in terms of quality assurance (QA) criteria used in the German ESB (B2.1). Sample-providing Beneficiaries (Fh-IME, UKCEH, Naturalis) tested the DCT for functionality and practicality, then filled out the DCTs with available data. EI constructed on-line Module 1 of the AP&P Knowledge Base (https://www.norman-network.com/apex/) based on the final DCT and uploaded the available data from Beneficiaries into the database.

In the DCT template, drop-down checklists have been designed for otter, buzzard, dolphin, seal and fish species to be gathered within the project. The second tab of the template gives an example how UKCEH (UK) has entered their data for buzzard.

Following the attendance of 16 selected R&T Partners at the LIFE APEX Workshop in Bratislava (January 2019) they were asked for input to the final design of the LIFE APEX Sample Catalogue (Sample Collection Metadata) Database (**see document submitted with the Mid-term report on 27/02/2020** – "Deliverable B.1.3, Annex 2") considering an optimum way of reporting information on both (a) APEX predator specimens (carcasses) they might have in their freezers, and (b) APEX predator tissue samples ready for contaminant analysis.

B3.2 Construction and population of Module 2: APEX Target Analyses Database (Lead EI, Support all ABs) Status: Completed

EI and all Associated Beneficiaries (ABs) reviewed the existing Biota DCT of the NORMAN EMPODAT database and advised on any necessary adjustments to accommodate AP&P chemical monitoring data. EI then adjusted as necessary the DCT and developed on-line Module 2 of the LIFE APEX Database System (https://www.norman-network.com/apex/lacod/), the 'Chemical Occurrence Database' (the login details are: Login: lifeapex, Password: lifeapex). UoA, EI, Fh-IME (former AB) and UNIFI completed the new Biota DCT (**see document submitted with the Mid-term report on 27/02/2020** – "Deliverable B.3.2, Annex 1") with data resulting from Action B4 (Tier 1) target

analyses. EI uploaded this data to Module 2 (see https://www.norman-network.com/apex/). Additionally, EI uploaded available data on biota samples from the NORMAN Database System (https://www.norman-network.com/nds/empodat/) to allow for comparison with existing datasets and started preparations for upload of large datasets of biota target analyses results from the database system of UBA. The updated and final version of the DCT for biota is submitted with this report (Annex 4).

At the end of the reporting period, the database contained 953,444 data entries on 3,253 targeted substances (end of October 2022). Tier 1: Altogether, 157,286 data entries on 2,227 targeted substances (of which 2,127 analysed by UoA, 56 by EI, 1 by Fh-IME and 43 by UNIFI), Tier 2: Altogether, 162,057 data entries on 2,227 targeted substances, Tier 3: Altogether, 154,026 data entries on 2,226 targeted substances (without Fh-IME).

B3.3 Construction and population of Module 3: APEX NTS Analyses Database (Lead EI, Support all ABs) Status: Completed

EI and UoA reviewed the existing NORMAN Digital Sample Freezing Platform (DSFP; https://dsfp.norman-data.eu/) DCT for NTS data (**see document submitted with the Mid-term report on 27/02/2020** – "Deliverable B.3.3, Annex 1"), which has previously been tested in several NORMAN NTS Collaborative Trials. The updated and final version of the DCT is submitted with this report (Annex 5). DSFP and its DCT were originally developed to store NTS data from water and indoor environment samples. The DCT was therefore adjusted (adding specific fields) to accommodate NTS data from biota. DSFP is already fully functional for liquid chromatography-high resolution-mass spectrometry (LC-HR-MS) data, and the gas chromatography-mass spectrometry (GC-MS) functionality has been tested. Module 3 of the LIFE APEX Database System (https://www.norman-network.com/apex/) is an integral part of DSFP providing an independent password protected access to samples analysed within the project. Module 3 gathers and archives data from NTS analyses of each AP&P sample for their retrospective analysis. Like Module 2, integration of Module 3 with the pan-European NORMAN Database System (https://www.norman-network.com/nds/) assures After-LIFE sustainability and facilitates its regulatory use. DSFP is linked to the NORMAN Substance Database (https://www.norman-network.com/nds/susdat/), allowing screening of each sample for presence/absence of >107,000 chemicals and their transformation products with potential to enter and persist in the environment.

For the latest update of the list of substances whose presence/absence in the samples can be screened in AP&P samples see https://www.norman-network.com/apex/susdat/susdatSearchShow.php (107,167 substances). The screened samples (Tier 1 – Tier 3) are available for further in-depth screening in DSFP (https://dsfp.norman-data.eu/dataset/27df0a3e-3578-4a30-b9e4-1505f9da010d).

B3.4 Population of the AP&P KnowledgeBase with data from R&T partners (Lead UBA - lead for ESBs, Support Naturalis - lead for NHMs, UoA - data upload) Status: Completed

In the first reporting period, UBA and Naturalis invited key R&T Partners (ESBs, NHMs – see Action B1) to provide data for Module 1 of the LIFE APEX Database System using DCT developed in B3.1. EI uploaded this data into the LIFE APEX Sample Catalogue. 14 datasets provided by Associated Beneficiaries and R&T partners were available at the end of the first reporting period, covering collections of nine species with more than 223,200 individual samples in five countries (Germany, Netherlands, Norway, Spain, UK). We invited ABs and R&T partners to provide also their available chemicals occurrence data from targeted analyses for Module 2 of the LIFE APEX Database System. At the further stage of the project, we contacted other R&T partners to provide the DCTs with information on available samples in their Sample Collections, at the end of the project we collected the DCTs from 75 sample collections (104 entries: https://www.norman-network.com/apex/catalogue/) across Europe (National History Museums and Environmental Specimen Banks). We collected the data from the following countries: Austria, Czech Republic,

Denmark (+ Greenland), Estonia, Finland, France, Greece, Hungary, Iceland, Italy, Lithuania, Portugal, Romania, Russia, Slovenia, Sweden, Switzerland, Turkey and Ukraine.

The planned and predicted outputs of Action B.3 were proceeding according to the LIFE APEX plan. No deviations have been identified.

The Action was closely following rapid developments in wide-scope target screening and NTS within the NORMAN network and its Database System (https://www.norman-network.com/nds/) in order to ensure full inter-operability of data at end of project. The NORMAN Database System represents current global state-of-the-art in monitoring and assessment of impacts of emerging substances in the environment. It has been agreed with EC JRC that LIFE APEX data from targeted analyses will be shared with the European community via the Information Platform for Chemical Monitoring (IPCheM), helping to ensure early impact of project findings on regulators.

This Action was a Key Element for replication and transfer, scale-up and sustainability of the project approach. The output is a European 'AP&P Knowledge Base' enhancing access to AP&P specimens and samples and to contaminant data in AP&P samples. This involves developing a web-based, open access database, with three inter-linked modules (cf. above). The AP&P Knowledge Base aims to become a tool for regulators and industry (and others) to access relevant chemical monitoring data and see who is doing what in terms of sampling, sample storage and sample analysis. It will also allow users to query raw quality-controlled monitoring data. The database modules were tested with regulators and industry and feedback was applied for their further improvement. All data collected within the project will be made publicly accessible at end of project via the NORMAN Database System (NDS): https://www.norman-network.com/nds/.

ACTION B4: DEMONSTRATOR 1:
Revealing presence of chemical contaminants in AP&P samples through target and non-target screening (NTS) analyses

Foreseen start date:	**Q4 2018 (1 October 2018)**
Actual start date:	**Q4 2018 (1 October 2018)**
Foreseen end date:	**Q3 2021 (30 September 2021)**
Actual end date:	**Q3 2021 (30 September 2021)**

B4.1 Gather samples for Tier 1 analyses, transfer to UoA for lyophilisation (Lead EI) Status: Completed

Tier 1 LIFE APEX samples have been collected (**see document submitted with the Mid-term report on 27/02/2020** – "Deliverable B.4.1, Annex 1"); species: Bream, Roach, Eelpout, Eurasian Otter, Harbour Seal, Harbour Porpoise, Buzzard, Herring gull, Herring, Grey Seal. In total, 67 LIFE APEX samples were obtained from Germany (24 samples), United Kingdom (20), the Netherlands (10) and Nordic region (13) and transferred to UoA for lyophilisation. Whenever necessary CITES permits were issued for the sample transport following the guidelines developed in the project (available here: https://lifeapex.eu/documents/).

B4.2 Distribute and extract Tier 1 samples in analytical labs for analysis (Lead EI) Status: Completed

After lyophilisation, the samples were distributed and extracted in analytical labs for analysis. UoA distributed aliquots of lyophilised samples among EI, Fh-IME/former AB, UoA and UNIFI for extraction and target and NTS analyses. Extraction and analytical methods used were described and harmonised in advance (Action B2). Analytical work was distributed as follows: UoA – target analysis of >2100 substances by LC-HR-MS; NTS by LC-HR-MS; target analysis of well-known substances: PFAS (PFSA, PFCA, PFOS, PFOA, PFHxSA, PFNA and PFDA, and their precursors); EI – NTS by GC-MS (EI/PCI/NCI modes); target analysis of well-known substances including dioxins and dioxin-like compounds (using cost-efficient bioassays and in case of positive finding confirmation with HRGC-HRMS); chlorinated alkanes (C10-13; C14-17 etc. using (GCx)GC-MS in NCI mode), novel organophosporous flame retardants and Dechlorane Plus; Fh-IME - target analysis of mercury; UNIFI - target analysis of well-known substances including PCBs, OCPs, PBDEs and Hexabromocyclododecane (HBCDD).

B4.3 Collect all Tier 1 data from target and NTS analyses in DCTs (Lead EI) Status: Completed

Analytical results were collected in DCTs (see Action B3) separately developed by EI for each partner's target list of substances and NTS analyses – and sent for processing at EI. After quality check the data was inserted by EI into the LIFE APEX Database System for target (Chemical Occurrence Data; https://www.norman-network.com/apex/lacod/) and NTS (DSFP; https://dsfp.norman-data.eu) database modules (see Action B3; sub-action B.4.3). Altogether, 157,286 data entries on 2,227 targeted substances (of which 2,127 analysed by UoA, 56 by EI, 1 by Fh-IME and 43 by UNIFI) were obtained. In addition to LC-HR-MS analyses, UoA performed GC-APCI-HR-MS data of all samples and results are ready for retrospective analysis of substances which are not amenable to LC analysis. Moreover, GC-MS of 66 samples (there was insufficient material available for one of the 67 samples) in modes of electron impact (EI), positive (PCI) and negative (NCI) chemical ionisation was carried out by EI and results are ready for retrospective analysis of suspect substances.

B4.4 Gather samples for Tier 2 analyses, transfer to UoA for lyophilisation (Lead EI) Status: Completed

An additional 68 samples (i.e., additional to the 67 collected for Tier 1) have been collected for Tier 2 analyses and transferred to UoA for lyophilisation; species: Bream, Harbour Seal, Buzzard, Eurasian Otter. 68 LIFE APEX samples were obtained from Germany (31 samples), United Kingdom (37 samples). Whenever necessary CITES permits were issued for the sample transport following the guidelines developed in the project (available here: https://lifeapex.eu/documents/).

B4.5 Distribute and extract Tier 2 samples in analytical labs for analysis (Lead EI) Status: Completed

After lyophilisation, the samples were distributed and extracted in analytical labs for analysis. UoA distributed aliquots of lyophilised samples among EI, Fh-IME/former AB, UoA and UNIFI for extraction and various targeted and NTS analyses (action B.4.2). Special attention was paid to fine-tuning/development of methodologies for analysis in all samples of top substances prioritised in Action B5. Analytical work was distributed as follows: UoA – target analysis of >2100 substances by LC-HR-MS; NTS by LC-HR-MS; target analysis of well-known substances: PFAS (PFSA, PFCA, PFOS, PFOA, PFHxSA, PFNA and PFDA, and their precursors); EI – NTS by GC-MS (EI/PCI/NCI modes); target analysis of well-known substances including dioxins and dioxin-like compounds (using cost-efficient bioassays and in case of positive finding confirmation with HRGC-HRMS); chlorinated alkanes (C10-13; C14-17 etc. using (GCx)GC-MS in NCI mode), novel organophosporous flame retardants and Dechlorane Plus; Fh-IME - target analysis of mercury; UNIFI - target analysis of well-known substances including PCBs, OCPs, PBDEs and Hexabromocyclododecane (HBCDD).

B4.6 Collect all data from Tier 2 target and NTS analyses in DCTs (Lead EI) Status: Completed

Analytical results were collected in DCTs (see Action B3) separately developed by EI for each partner's target list of substances and NTS analyses – and sent for processing at EI. After quality check the data was inserted by EI into the LIFE APEX Database System for target (Chemical Occurrence Data; https://www.norman-network.com/apex/lacod/) and NTS (DSFP; https://dsfp.norman-data.eu) database modules (see Action B3; sub-action B.4.3). Tier 2: Altogether, 162,057 data entries on 2,227 targeted substances were obtained. In addition to LC-HR-MS analyses, UoA performed GC-APCI-HR-MS data of all samples and results are ready for retrospective analysis of substances which are not amenable to LC analysis. Moreover, GC-MS of samples in modes of electron impact (EI), positive (PCI) and negative (NCI) chemical ionisation was carried out by EI and results are ready for retrospective analysis of suspect substances.

See Deliverable B.4.2, Annex 1.

B4.7 Identify R&T partners with relevant samples, gather samples for Tier 3 analyses, transfer to UoA for lyophilisation (Lead EI) Status: Completed

The samples were obtained through existing networks of the Associated Beneficiaries (COST Action: https://erbfacility.eu/, Otter project: https://www.cardiff.ac.uk/otter-project, ESBs and other sample collections). The pooled samples of the same AP&P species used in Tier 1 and Tier 2 were gathered from R&T partners and analysed, to replicate the Tier 1 approach and derive a wider European picture of occurrence of contaminants in AP&P. UBA and Naturalis led on gathering samples from ESBs and NHMs respectively. Invited R&T partners (ESBs, NHMs; see Action B1) provided the 63 samples from the following countries: Sweden (4), Germany (3), Italy (4), France (1), Austria (2), United Kingdom (9), Denmark (4), Czech Republic (3), Norway (4), Hungary (3), Spain (8), Ukraine (1), Poland (2), Belgium (5), Slovakia (2), Greece (2), Slovenia (2), Portugal (2) and Romania (2). Samples were sent to UoA for lyophilisation; species: Eurasian lynx, White-tailed Sea Eagle, Grey Seal, Eurasian Otter, Bottlenose dolphin, Harbour Porpoise, Striped dolphin, Short-beaked common dolphin, White-beaked dolphin, Ringed Seal, Bearded Seal, Harbour Seal and Buzzard.

B4.8 Distribute and extract Tier 3 samples in analytical labs for analysis (Lead EI) Status: Completed

After lyophilisation, the freeze-dried samples were distributed and extracted in analytical labs for analysis. UoA distributed aliquots of lyophilised samples among EI, UoA and UNIFI for extraction and various targeted and NTS analyses (action B.4.2). Special attention was paid to fine-tuning/development of methodologies for analysis in all samples of top substances prioritised in Action B5. Analytical work was distributed as follows: UoA – target analysis of >2100 substances by LC-HR-MS; NTS by LC-HR-MS; target analysis of well-known substances: PFAS (PFSA, PFCA, PFOS, PFOA, PFHxSA, PFNA and PFDA, and their precursors); EI – NTS by GC-MS (EI/PCI/NCI modes); target analysis of well-known substances including dioxins and dioxin-like compounds (using cost-efficient bioassays and in case of positive finding confirmation with HRGC-HRMS); chlorinated alkanes (C10-13; C14-17 etc. using (GCx)GC-MS in NCI mode), novel organophosporous flame retardants and Dechlorane Plus; UNIFI - target analysis of well-known substances including PCBs, OCPs, PBDEs and Hexabromocyclododecane (HBCDD).

B4.9 Collect all data from target and NTS analyses in Data Collection Templates (Lead EI) Status: Completed

Analytical results were collected in DCTs (see Action B3) separately developed by EI for each partner's target list of substances and NTS analyses – and sent for processing at EI. After quality check the data was inserted by EI into the LIFE APEX Database System for target (Chemical Occurrence Data; https://www.norman-network.com/apex/lacod/) and NTS (DSFP; https://dsfp.norman-data.eu) database modules (see Action B3; sub-action B.4.3). Tier 3: Altogether, 154,026 data entries on 2,226 targeted substances (without Fh-IME). In addition to LC-HR-MS analyses, UoA performed GC-APCI-HR-MS data of all samples and results are ready for retrospective analysis of substances which are not amenable to LC analysis. Moreover, GC-MS of samples in modes of electron impact (EI), positive (PCI) and negative (NCI) chemical ionisation was carried out by EI and results are ready for retrospective analysis of suspect substances.

See Deliverable B.4.3, Annex 1 and Deliverable B.4.4, Annex 1.

The planned and predicted outputs of Action B.4 were proceeding according to the LIFE APEX plan. No deviations have been identified.

This demonstrator took a three-tiered approach:

Tier 1: Wide-scope screening: Each sample was subjected to 3 types of chemical analyses: (1) target analysis of substances known to be frequently occurring in biota; (2) target analysis of >2,100 emerging contaminants frequently appearing in environmental matrices and (3) non-target screening (NTS) by two complementary techniques: LC-HR-MS operated in positive and negative ion mode; and GC-MS operated in electron impact (EI), positive (PCI) and negative chemical ionisation (NCI) modes.

Data from all samples were screened for presence/absence of REACH chemicals (at present ca. 60,000 available on the ECHA website) and organic biocides. Information needed for screening is already available (through NORMAN) for ca. 66,000 suspect chemicals and their characteristic transformation products (another c. 20,000 chemicals were added by end 2020) (see Action B3).

Tier 2 - Time trend analyses: We were gathering and analysing a time-series (2000-2018) of 1 pooled sample (i.e., several samples pooled together) per year for 3 of the Tier 1 species from one of the Tier 1 locations in one of the Tier 1 countries. Samples were sent to UoA for lyophilisation, and after processing were sent to labs (EI, Fh-IME/former AB, UoA, UNIFI) for extraction and analysis using the same 3 methods. We made fine-tuned analyses for the top 10 APEX target substances and top 10 APEX unambiguously identified substances (from NTS) resulting from prioritisation (Action B5).

Tier 3: Pooled samples of the same AP&P species used in Tier 1 and Tier 2 were gathered from R&T partners and analysed, to replicate the Tier 1 approach and derive a wider European picture of occurrence of contaminants in AP&P. This Tier 3 analysis focussed on TOP APEX substances prioritised in Action B5. UBA and Naturalis led on gathering samples from ESBs and NHMs respectively.

The report on methodologies used and overview of data obtained by Tier 1 (wide-scope screening), Tier 2 (time trend analysis) and Tier 3 (replication) is submitted with this report (Deliverable B.4.4, Annex 1).

Outside LIFE APEX, a parallel screening of biota samples using LIFE APEX methodology took place in the Black Sea region (EU/UNDP EMBLAS+ project; six countries; 2019) and Joint Danube Survey 4 (JDS4, ICPDR, 14 European countries; 2019). The biota samples from OSPAR (North-East Atlantic countries) region were analysed using the same workflow as in LIFE APEX in 2020 and 2021. Similarly, biota samples from HELCOM (Baltic Sea countries) were analysed in 2021 and 2022. This included analyses of marine mammals within a separate UBA-HELCOM project in 2021.

The objective of this Action was to demonstrate how state-of-the-art chemical screening can be used to detect presence of wide-scope chemicals in AP&P samples. Such data is of particular regulatory value for prioritisation of chemicals for PBT assessment (Action B5) and to determine predominant mixtures (Action B7). Once the potential of using screening data from the AP&P samples from ESBs and NMHs is fully acknowledged by European Commission and its services, the established methodologies will be used in a wide European, and possibly, global context for regulatory purposes. The NORMAN network has agreed to continue this task beyond end of project.

ACTION B5: DEMONSTRATOR 2:
Prioritisation of the most relevant contaminants in AP&P samples and assessment of the applicability of such monitoring data for PBT assessment in the European regulatory context

Foreseen start date:	**Q3 2019 (1 July 2019)**
Actual start date:	**Q3 2019 (1 July 2019)**
Foreseen end date:	**Q1 2022 (31 March 2022)**
Actual end date:	**Q1 2022 (31 March 2022)**

B5.1 Prioritisation of target substances (Lead EI, Support UoA, UBA) Status: Completed

To increase the scope of Tier 1, 2 and 3 wide-scope target screening UBA had prepared a list of chemicals, for which LIFE APEX data (target, suspect & non-target screening) could be supportive for chemical assessment and regulation (Deliverable B.5.1, Annex 1-Annex 5).

Chemicals detected in AP&P samples were firstly classified according to their legislations (REACH, Biocides, Pharmaceuticals, Plant Protection Products). In a second step, chemicals were assessed according to their frequency of appearance (FoA) in the respective analytical tier. The potential hazard of the remaining chemicals was estimated using the JANUS tool. In parallel, the chemicals were assigned P and B and T scores and ranked according to the NORMAN Prioritisation Framework. The proposed PBT criteria and cut-off values used in the JANUS tool (https://www.vegahub.eu/portfolio-item/janus/) are also compatible with those adopted in current regulations such as in Annex XIII of REACH. The tool can combine existing experimental data with various *in silico* prediction models and tools to predict P, B and T properties of substances. Each of these properties is given also an uncertainty value and finally the single P, B and T scores are combined to an overall PBT score (in the range between 0 and 1).

The test-runs for the JANUS tool were performed using the NORMAN compound list (>66,000) to make sure that the programme could handle large data sets.

Furthermore, for REACH compounds, the list provides information on the assessment and regulation status of each chemical based on the ECHA Public Activities Coordination Tool (PACT). For substances that are currently under assessment due to potential PBT properties, data on the occurrence in biota would be very helpful for the further bioaccumulation assessment. Already regulated substances include chemicals, which have been previously identified as PBT or similar hazardous substances. Due to their accepted B status (BCF > 2,000 L/kg), these PBT chemicals are expected to accumulate in biota and (depending on the emission and use patterns) will likely be detectable in higher trophic species, e.g., top predators. For these chemicals data in apex predators and prey are supportive in order to check if the initiation and enforcement of mitigation measures under the different regulations have led to reduction of environmental emissions and accumulation.

B5.2 Prioritisation of NTS substances (Lead EI, Support UoA) Status: Completed

Prioritisation was performed at several 'levels of confidence' at which the substance was analytically identified (targeted; suspect screening). With regard to NTS, only a few tens were unambiguously identified among the 100–300 substances detected in each sample; many assigned a name with a certain probability, for most we knew only mass and mass spectrum (fingerprint). Chemicals with unknown ID were not further treated. Data generated by UoA (LC-HR-MS) and EI (GC-MS) were transferred (Action B4) into DCTs. Prioritisation of substances (B5.1-B5.4) was primarily based on the Frequency of Appearance (FoA; see B5.1) resulting in 440 TOP APEX REACH suspect substances (B5.2) and only 1 TOP APEX REACH target substance (B5.1.) from Tier 1, 2 and 3 analysis (198 samples in total). UBA compiled additional information on regulatory status, use, tonnage and ecotoxicity of REACH chemicals and applied the JANUS QSAR tool to screen for potential hazardous properties of these 441 TOP APEX substances. Among the 441 TOP APEX chemicals, 67 non-regulated REACH chemicals were identified that potentially pose a risk for the

environment due to potential persistent and bioaccumulative properties (B5.3). These have been assessed in more detail by UBA (see 67 fact sheets). The LIFE APEX list of all chemicals identified was shared with ECHA and several EU environment agencies to discuss upon alternative prioritization schemes and to trigger regulatory use of the data. UoA provided its unique Europe-wide accepted modelling software to calculate Retention Time Index (RTI) for each detected substance which is needed to 'boost the level of confidence' (substance identified based on mass spectral 'fingerprint' and retention time). See Deliverable B.5.1.

B5.3 PBT assessment and ranking of prioritised substances (Lead UBA) Status: Completed

REACH substances prioritised in B5.1 based on the FoA (≥50%) and JANUS PBT/vPvB scores (≥0.3) were additionally manually screened for P, B and T properties based on the information in the open accessible registration dossiers on the ECHA dissemination site. The manual PBT assessment on the screening level was performed for all 67 prioritised substances that are currently not under assessment/regulation according to their previously known PBT or vPvB properties. Based on the outcome of the PBT status and exposure considerations (e.g., use, tonnage), the substances were ranked for in depth PBT assessment and further regulatory activities.

B5.4 Exposure assessment and ranking of prioritised substances (Lead Fh-IME/former AB, Support UBA) Status: Completed

The Exposure Index developed by KEMI, Sweden for the NORMAN network (https://zenodo.org/record/3653175#.XlVLF2hKg2w) was used to assess and rank overall hazard stemming from use of individual substances. The score has been developed based on the substance use pattern. It consists of three parts: (i) the degree of uncontrolled release during use; (ii) the quantity used and (iii) the wideness of the use on the market.

This Index takes into account different tonnages, usages and other parameters and has so far been applied for more than 65,000 chemicals including those from REACH and biocides regulations. The Exposure Index converts this business-sensitive information (provided by industry to REACH) to an index value between 0 (no exposure) and 1 (maximum exposure) and can be used to assess overall exposure to the compound. The Exposure Index could be applied for biocides since data on their production volumes and amounts used are lacking. The index was therefore adjusted by Fh-IME (former AB) based on the outcomes of the previous Europe-wide project *"Environmental monitoring of biocides in Europe - compartment-specific strategies"* and then applied by UBA for the prioritised top 300 AP&P pollutants.

B5.5 A draft guideline for the assessment of bioaccumulation of relevant pollutants in AP&P samples (Lead UBA, Support Fh-IME/former AB) Status: Completed

A draft guideline was developed (Deliverable B.5.2, Annex 1 and Annex 2) on how to assess results from target and NTS analyses of AP&P samples archived in ESBs and NHMs in Europe in a regulatory context. The guideline was proposed to ECHA and MSCAs at the Final conference. In parallel, a substance evaluation (SEv) similar to ECHA procedures was carried out for 1–2 substances of PBT concern; the B criterion was assessed based on monitoring and other data, as far as available, in a weight-of-evidence approach (Deliverable B.5.3, Annex 1-Annex 3). The final conference developed ideas for After LIFE promotion of the draft guideline in the regulatory and scientific context.

The planned and predicted outputs of Action B.5 proceeded according to the LIFE APEX plan. No deviations have been identified.

The objective of this Action was to demonstrate how wide-scope chemical screening data can be used to prioritise the most relevant substances for further hazard (PBT) assessment under REACH and BPR. PBT assessment was conducted in a similar way under REACH and BPR as both apply the criteria described in REACH Annex XIII. The PBT/vPvB screening and assessment process is a

challenging task. Assessors (authorities, registrants) face tens of thousands of potential PBT substances and are often confronted with complex tasks on how to evaluate and integrate field and monitoring data. ECHA Guidance on Information Requirements (chapters R11, R7b and R7c and BPR vol II B & C) describes opportunities to use monitoring data in the evaluation of persistence (P) and bioaccumulation (B) in a 'weight-of-evidence' approach. This Action aimed to show how chemical monitoring data can be used to facilitate prioritization for further hazard assessment, in particular for bioaccumulation assessment of a potential PBT substance. Action B4 delivered >13 million data entries from target and NTS analyses and store these in the APEX KnowledgeBase (Modules 2 and 3). Action B5 showed how such data can be assessed to select top ranking pollutants (in terms of frequency of appearance in the environment and PBT profile) as candidates for further PBT assessment.

LIFE APEX closely cooperates with the NORMAN network in terms of developing its prioritisation scheme. The previous scheme (https://www.norman-network.net/sites/default/files/files/Publications/NORMAN_prioritisation_Manual_15%20April2013_final%20for%20website-f.pdf) is currently being updated to accommodate also NTS results. An automated routine for prioritising substances is being developed and all LIFE APEX substances would undergo this procedure if accepted Europe-wide.

LIFE APEX is setting up a novel prioritisation/risk assessment scheme of chemical contaminants in biota, bringing together the leading research groups in Europe (ESBs, NHMs, RCs and NORMAN partners). The aim is to establish a state-of-the-art workflow feeding the need of regulators managing risks of chemicals in the environment in Europe. There is a potential that the approach will be followed by the rest of the world.

ACTION B6: DEMONSTRATOR 3:
Demonstrating use of raptor chemical monitoring data to assess impact and effectiveness of risk mitigation measures at national and European scales

Foreseen start date:	**Q3 2018 (1 September 2018)**
Actual start date:	**Q3 2018 (1 September 2018)**
Foreseen end date:	**Q1 2022 (31 March 2022)**
Actual end date:	**Q1 2022 (31 March 2022)**

B6.1 Literature review to provide proof of concept and elucidate key issues (Lead UKCEH/former CEH) Status: Completed

We have reviewed literature on AP&P monitoring that shows reduction in legacy POPs across Europe following RMM/bans, to provide proof of concept that declines can be detected using AP&P. This also helped to elucidate which species or species guilds might be used for monitoring change at pan-European scale, likely time-lags between implementation of restrictions and changes in environmental concentrations, and how and why rate of change varies between species, compound and spatially.

B6.2 Guidelines on use of raptor samples to monitor changes in pollutants (Lead UKCEH/former CEH) Status: Completed

We have assessed the utility of different species (and species guilds – read-across between closely related species is likely to be necessary for pan European coverage) and tissues for monitoring change in contaminant concentrations. We have considered and agreed on compounds to be analysed for in B6.3 and B6.4. We have produced guidelines on use of raptor samples to monitor changes in terrestrial pollutants (**see document submitted with the Mid-term report on 27/02/2020** - "Deliverable B.6.1, Annex 1"). The study focussed on biomonitoring the European terrestrial environment for a set of priority pollutant groups through measurement of residues in tissues obtained from carcasses of raptors and owls found dead. Key traits that made species suitable for pan-European monitoring were widespread species distribution, feeding ecology and habitat selection.

B6.3 Demonstrate potential for pooling samples, impact of pooling on power to detect change in contaminant concentrations at county scale (Lead UKCEH/former CEH) Status: Completed

We demonstrated the capacity of pooled within-country samples to provide representative country-scale data on changes over time in average concentrations and demonstrate the power of monitoring with pooled samples.

We carried out time-series chemical analyses on ESB and NHM specimens for REACH and/or BPR substances subject to recent (or anticipated) RMM. These included one or more of: (a) polychlorinated biphenyls (PCBs) – internationally controlled under the Stockholm Convention 2001 and subject to increasing restrictions in the EU pursuant to this; (b) PBDEs including deca-BDE – subject to major restrictions on use from March 2019 under REACH; (c) Dechlorane plus - notified to the Registry of Intentions for Substances of Very High Concern in 2017; (d) Mercury – RMM under REACH and promised under Minamata; (e) Second generation anticoagulant rodenticides (SGARs) – biocides subject to a variety of restrictions in use across European countries.

64 livers of Common Buzzard *Buteo buteo* from the Netherlands were analysed for PCBs and PBDEs at the University of Florence. 72 livers of Common Buzzard from the UK were analysed for SGARs at UKCEH; and 72 livers of Common Buzzard from the UK were analysed for Hg at UKCEH. Thus, a total of 64 + 72 + 72 = 208 samples were analysed under B6.3 (instead of the foreseen 144 samples as planned in the Grant Agreement). The data (DCTs) are available in the LIFE APEX database: https://www.norman-network.com/apex/lacod/.

Sample years were chosen to include at least one year prior to RMM implementation and several years spread across the post-implementation period. Results for individual samples were compared with results obtained by simulating within-year pooling of those samples. We explored how far pooling samples from 12 individuals (in 6, 4, 3, 2 or 1 pooled samples p.a.) can give measurements that are representative of country-scale concentrations and enable detection of temporal trends. We examined trade-offs between extent of sample pooling, number of pooled samples that are analysed, and projection of the magnitude of change in environmental concentrations that would be detectable if monitoring were continued for 5 and 10 years. This informed our pooling strategy under B6.4 and the outcomes of limited time trend analyses in Action B4 (which relies on pooled samples). The outcome of work under B6.3 will be reported in the following papers (in preparation):

- A paper presenting the findings from the power analyses for PCBs, PBDEs, SGARs and Hg;
- A paper on PBDEs, Dechlorane plus and recent flame retardants in individual Buzzard livers from The Netherlands 1994-2020;
- A paper on PCBs, deca-BDE and total PBDE trends in individual Buzzard livers from The Netherlands 1994-2020;
- A paper on SGARs and Hg (and other metals) trends in individual Buzzard livers 2000-2020 from the UK.

B6.4 Demonstrate monitoring at pan-European scale (Lead UKCEH/formed CEH) Status: Completed

To demonstrate the approach at pan-European scale, UKCEH and UNIFI analysed pooled samples from 11 additional countries across Europe, for the same determinants as, and similar time frame to, B6.3. We used knowledge gained in B6.2 and B6.3 to decide on pooling 2 individual liver samples in each pooled sample. The number of pooled samples per country and the timeframe covered for each country was determined by the availability of samples. The overall timeframe for the 11 countries was 1996-2021. A total of 152 Buzzard liver samples were obtained from 21 collections (mostly Natural History Museums and some other Research Collections) in 11 countries across Europe (AT, BE, CH, DE, EL, ES, FI, IT, PT, RO, SI). Samples were shipped to UNIFI where pooling was done, providing 64 pooled samples (not all samples were of sufficient mass to be used). Each pooled sample was then divided into two parts, with one part analysed for PCBs and PBDEs at UNIFI, and the other part shipped to UKCEH and analysed for SGARs and Hg (and other metals). The data (DCTs) are available in the LIFE APEX database: https://www.norman-network.com/apex/lacod/.

This demonstrated variation in concentrations of selected compounds at European scale across space and time, following introduction of RMM, comparability of specimens from ESBs, NHMs and other Research Collections for tracking changes in concentrations, and the magnitude of change that can be detected after 5 and 10 years of monitoring.

The outcome of work under B6.4 will be reported in the following papers (in preparation):

- A paper on PCBs, PBDEs and Dechlorane plus trends in pooled Buzzard liver samples from 11 European countries 1996-2021;
- A paper on SGARs and Hg (and other metals) trends in pooled Buzzard liver samples from 11 European countries 1996-2021.

B6.5 Framework on generation and use of raptor chemical monitoring data to assess RMM outcomes at pan-European scale (Lead UKCEH/former CEH) Status: Completed

We produced a framework (consulted with the key R&T partners) on how appropriate data can be generated and used from ESB and NHM samples to assess effectiveness of RMM at pan-European scale, the cost-effectiveness of this approach and the likely power of such monitoring to detect change (Deliverable B.6.2, Annex 1).

The planned and predicted outputs of Action B.6 were proceeding according to the LIFE APEX plan. No deviations have been identified.

The objective was to show that chemical monitoring data from raptor samples from ESBs and NHMs can be used for wide-scale assessment of chemical risk mitigation measures (RMM). We identified key issues in using ESB samples, show that NHM samples can usefully complement ESB samples and develop guidelines for tracking changes in chemical concentrations in AP&P samples, taking into account sample pooling (to ensure monitoring is cost-effective, tractable and affordable) and scalability (national to pan-European). Actions B4 and B5 pertain largely to pre-assessment, demonstrating how monitoring can help prioritise compounds for assessment; B6 showed how monitoring can be used to assess impact of regulation post-assessment, in particular where assessment has been followed by implementation of RMM. RMM are typically applied to compounds that pose unacceptable environmental risk and range from national, EU-wide or global restrictions on amount or type of use, to total bans. There is at present no structured approach to assess effectiveness of RMM in terms of speed and extent of impact on environmental concentrations and exposures. REACH and other directives require a framework for tracking outcomes of RMM to assess if they are really working to protect human health and the environment. Raptors are well established as sentinels of environmental pollution and can be used to monitor temporal and spatial trends in contaminant concentrations. However, use of raptor monitoring data in a formal framework to assess RMM outcomes is rare. A challenge is to source enough samples from across Europe to obtain sufficient and representative spatial coverage. Samples from ESBs are crucial, but needed supplementing from other sources, the most accessible and substantial being NHMs.

The activities were closely inter-linked with the COST Action ‘European Raptor Biomonitoring Facility.’

It is expected that the outcomes of this activity will be critically considered by the regulators and, if accepted, regulatory monitoring schemes of AP&P samples will be established across Europe.

Two papers with B6 approach were published already (Deliverable B.6.3, Annex 1, Annex 2), other papers are under preparation as mentioned above.

ACTION B7: DEMONSTRATOR 4:
Defining predominant chemical mixtures in AP&P samples
Foreseen start date: **Q1 2021 (1 January 2021)**
Actual start date: **Q1 2021 (1 January 2021)**
Foreseen end date: **Q4 2021 (31 December 2021)**
Actual end date: **Q4 2021 (31 December 2021)**

B7.1 Select and apply a battery of tools for statistical evaluation and visualisation of the data and identification of predominant chemical mixtures (Lead EI) Status: Completed

This action involved establishing and testing a workflow for high-throughput statistical analysis of target and NTS data and then implementing this workflow. Concentrations of chemicals determined in AP&P samples from target analyses, semi-quantitative assessments of concentrations from analyses of suspect chemicals and normalised intensity of signals from NTS analyses were used to 'weight' the significance of presence of individual detected substances in the mixtures.
The presence/absence of individual chemicals in studied AP&P matrices were assessed using co-occurrence graph databases and statistical tools in order to determine predominantly occurring mixtures. Co-occurrence map methods were used to interactively visualize the chemical fingerprints (https://norman-data.eu/LIFE_APEX_Mixtures/). For this reason, the open-source R programming language was used for statistical computing and analysis of 'big data'. R language is a well-recognized tool for high-throughput statistical analysis. The generated application was based on open-source packages from the official repository of R [1] and Bioconductor [2].
A customized NTS workflow was used to connect the output from LC-HR-MS (target and non-target screening) with other individual R libraries (e.g., xcms, nontarget, RAMClustR, CAMERA). The methodology and all the outputs of the chemicals mixtures analysis were shared through a report (list of predominant mixtures in AP&P samples, see Deliverable B.7.1, Annex 1).
Moreover, we selected and applied a range of multivariate and univariate parametric and non-parametric statistical tests to compare the chemical content of samples. Correlation analysis and unsupervised classification (e.g., decision trees) were used to find similar and unique patterns among the different biota species. The NTS workflow and the prioritization statistical tools that were selected for evaluation and visualization of the results are summarized in a manuscript, which will end up in a peer-reviewed publication at a journal with high impact factor.

ACTION C1:
Monitoring the impact of the project actions in relation to the specified performance indicators

Foreseen start date:	**Q3 2018 (1 September 2018)**
Actual start date:	**Q3 2018 (1 September 2018)**
Foreseen end date:	**Q3 2022 (31 August 2022)**
Actual end date:	**Q3 2022 (31 August 2022)**

C1.1 Finalisation of indicators and development of data collection methods to monitor progress on indicators (Lead EI) Status: Completed

This has involved refining a set of Key Performance Indicators through the LIFE KPI module (Annex 7), pertinent to the project goal, aim, objectives and expected impacts. A set of Project Specific Indicators identified at proposal stage has also been finalised and agreed (**see document submitted with the Mid-term report on 27/02/2020** - "Deliverable C.1.1").

C1.2 Development of a baseline report (Lead EI) Status: Completed

This has involved developing a baseline in relation to the selected indicators, against which project performance can be assessed (**see document submitted with the Mid-term report on 27/02/2020** - "Deliverable C.1.2"). The baselines for the LIFE KPIs have been set in the KPI module.

C1.3 Progress, Mid-term and Final evaluations (Lead EI) Status: Completed

These involved a review of project progress in relation to the planned milestones and deliverables and in relation to the selected performance indicators. It was led by the Project Coordinator with input from the external Reporting and Risk Expert. All Beneficiaries were contributing to these evaluations. Mid-term report was submitted on 27/02/2020 and Progress report was submitted on 25/06/2021 to the EC.

The Final evaluation is provided through this report.

C1.4 Ex post impact assessment including projecting outputs and impacts 3-5 years beyond the project period (Lead EI) Status: Completed

This involved an assessment, towards the end of the project, of the impact of the project in relation to expected outputs and expected longer-term impacts and in relation to the selected performance indicators. This assessment shows the expected impacts 3-5 years beyond the project period. This assessment was made in consultation with the main project stakeholders, including key R&T partners in the ESB and NHM communities, regulators and industry. This assessment was led by the Project Coordinator with input from the external Reporting and Risk Expert and all project Beneficiaries (Deliverable C.1.3, Annex 1).

C1.5 Assessment of socio-economic impacts of the project actions (Lead EI) Status: Completed

This involved an assessment, towards the end of the project, of the socio-economic impacts of the project, with reference to those expected socio-economic impacts. This was done in consultation with key stakeholders including regulators and industry. It was led by the Reporting and Risk Expert (Deliverable C.1.4, Annex 1).

The planned and predicted outputs of Action C.1 were proceeding according to the LIFE APEX plan. No deviations have been identified.

The objective of Action C.1 was to monitor outputs and impacts of the action in relation to selected LIFE Performance Indicators and LIFE APEX Project Specific Indicators. LIFE APEX monitored the project outputs and impacts, within the context of the project's goal, aim and objectives, over the lifetime of the project, and projected the impacts 3-5 years beyond project lifetime. The long-term goal of LIFE APEX is to reduce human and wildlife exposure to harmful chemicals in the

environment. LIFE APEX aims to contribute to this goal by responding to needs of regulators (ECHA, Member State Competent Authorities) in relation to the use of chemical monitoring data. The short-term aim of the project is to improve systematic use, by regulators, of chemical monitoring data from apex predators and prey ('AP&P') for better chemicals management, thereby reducing exposure to harmful substances and protecting human health and the environment. Project objectives, actions and expected outputs towards meeting the above short-term aim and long-term goal are an important source of reference for the development of performance indicators. Perhaps of greatest pertinence, however, to the design of performance indicators are the expected longer-term impacts repeated here. They are: (1) Wide engagement of ESBs, NHMs and other collections and labs in generating high quality contaminant data from AP&P samples; (2) A growing body of available, accessible, comparable and interoperable contaminant data from AP&P, attuned to regulatory needs; (3) Substantial use, by regulators, of this data, for: (a) more cost-effective and earlier detection of contaminants and predominant mixtures in the environment; (b) more cost-effective prioritisation of substances for hazard assessment, and better accounting in hazard assessment for environmental presence of substances; (c) enhanced consideration and understanding, by regulators, of the effectiveness of risk mitigation measures, leading to improved risk mitigation measures; (4) Reduced human and wildlife exposure to harmful substances, protecting human health and the environment.

It is expected that LIFE APEX will set up a truly European platform for systematic use of state-of-the-art analyses of AP&P samples interlinked with the harmonised assessment of the adverse properties of detected chemicals to support European chemicals management policy.

ACTION D1:
Development of general dissemination and communications strategy and implementation of the strategy's actions

Foreseen start date:	**Q3 2018 (1 September 2018)**
Actual start date:	**Q3 2018 (1 September 2018)**
Foreseen end date:	**Q3 2022 (31 August 2022)**
Actual end date:	**Q3 2022 (31 August 2022)**

D1.1 Development of dissemination and communications strategy and action plan (Lead EI) Status: Completed

A dissemination and communication strategy has been developed (**see document submitted with the Mid-term report on 27/02/2020** – "Annex 4"). The strategy aimed to optimise the impact of LIFE APEX Implementation Actions B1-B7 with key users and raise general awareness of the value of chemical monitoring data from AP&P. The strategy was developed and updated on an annual basis and its implementation is monitored by the Dissemination and Communication Sub-Group (Action E1).

D1.2 Development of LIFE APEX corporate identity (Lead EI) Status: Completed

A LIFE APEX logo (**see document submitted with the Mid-term report on 27/02/2020** - "Deliverable D.1.1, Annex 2") and LIFE APEX flyer (**see document submitted with the Mid-term report on 27/02/2020** – "Deliverable D.1.1, Annex 1") have been created. The project Newsletter (7 issues) can be downloaded from the project website: https://lifeapex.eu/dissemination/. The LIFE APEX flyer (**see document submitted with the Mid-term report on 27/02/2020** – "Deliverable D.1.1, Annex 1") was placed at each Beneficiary's office at strategic places accessible to the public (thereby serving as a Notice Board).

D1.3 Promotion of the project's results (Lead EI) Status: Completed

A project website has been created (https://lifeapex.eu/) and presents background, objectives and structure of the LIFE APEX project, as well as list of project Beneficiaries, list of LIFE APEX Regulatory Advisory Board (RAB) members, implementation actions with Beneficiary responsible for the action, current status of the project actions, dissemination of the project's results in the form of Newsletter (7 issues) (https://lifeapex.eu/dissemination/), project publications and posters presented at international conferences (**see document submitted with the Mid-term report on 27/02/2020** – "Deliverable D.1.3").

The LIFE APEX Newsletters were prepared in accordance to the schedule of the project meetings and disseminated among project beneficiaries, R&T Partners, RAB members, questionnaire participants and interested third parties. Newsletters have been prepared in January 2019, May 2019, September 2019, March 2020, December 2020, October 2021 and May 2022. The promotional video of LIFE APEX project has been released (see https://lifeapex.eu/). The video was created by an external expert (Oleksandr Kurta), selected by the procurement procedure. A LIFE APEX Internal Area was created on the website for project Beneficiaries in order to provide internal project documents as well as presentations from workshops and project meetings. A LIFE APEX Internal Area for external partners (RAB members, R&T partners) was also created on the website in order to ensure more involvement in the project and disseminate project results among R&T partners. The webpage maintains four database modules: Substance Database, LIFE APEX Sample Catalogue, LIFE APEX Chemical Occurrence Data and Digital Sample Freezing Platform. Furthermore, it contains background information on the sampled apex predators and their prey species, the implementation of LIFE APEX actions, as well as publications.

On-going LIFE APEX activities are also presented in LIFE APEX Twitter account (https://twitter.com/LIFEAPEX1). The account is regularly updated. A total of 97 people/institutions are currently (26/09/2022) following the LIFE APEX Twitter account. Tweets are generally re-tweeted by colleagues and interested third parties, which increases the visibility of the project.

Furthermore, a project has been initiated on ResearchGate (https://www.researchgate.net/project/LIFE-APEX-Project), the social networking site for scientists and researchers, to increase the visibility of publications and network with similar projects. 32 researchers are following the LIFE APEX project on ResearchGate. UBA has initiated an on-line questionnaire on the use and needs for monitoring data, including apex predators. In the questionnaire, institutions involved in chemicals regulation showed a high interest in receiving updates via the LIFE APEX questionnaire and the dissemination list is regularly updated.

D1.4 Wide public involvement (Lead EI) Status: Completed

Information about the project has been translated into brochures, printed and downloadable text from the project website: https://lifeapex.eu/ (**see document submitted with the Mid-term report on 27/02/2020 –** "Deliverable D.1.2, Annex 1, Annex 2") and allowed for distribution of this information at various events attended by the project Beneficiaries and external partners (assemblies of ESBs, NHMs, scientific and other stakeholder conferences, etc.) in order to achieve wider public involvement.

Layman's report (Deliverable D.1.5, Annex 1) involved the translation of key project deliverables into layman's language, downloadable from the project website (and from the websites of project partners) in order to distribute it at various events attended by the project partners (assemblies of ESBs, NHMs, scientific and other stakeholder conferences, etc.). It condensates the text from brochures into press releases and invites relevant national, European- and global- coverage media for press conferences to share outcomes of the project.

We produced also a short (5-7 min) LIFE APEX video covering all aspects of AP&P sampling, storage, analysis and political implications of the results and we shared it via the project website (www.lifeapex.eu) and stakeholders' networks.

D1.5 Networking with other projects and networks (Lead UBA) Status: Completed

Collaboration between LIFE APEX and other projects and networks has been established, including NORMAN Association (N° W604002510) – a network of reference laboratories, research centres and related organisations for monitoring of emerging environmental substances (more than 80 organisations dealing with emerging substances in environment), the COST Action ERBFacility (with representatives from 27 COST Member Countries), HBM4EU (UBA, the largest European network addressing human biomonitoring with c. 40 lead partners and c. 80 linked partners from across Europe), the International ESB Group, CETAF (which brings together NHMs and other collections), OSPAR (https://www.ospar.org/), HELCOM (https://helcom.fi/) Regional Sea Conventions at their various expert group meetings.

The LIFE APEX approach is currently being implemented by the OSPAR Commission (https://www.ospar.org/) to gather a critical mass of data for an update of the North-East Atlantic specific list of contaminants. Similarly, HELCOM Commission (https://helcom.fi/) followed in the Baltic Sea region. LIFE APEX was also presented by Jaroslav Slobodnik (EI) on THE EIONET AD-HOC EXPERT GROUP ON CHEMICALS meeting: Chemicals strategy for sustainability (26–27 January 2021), organised by German Environment Agency (UBA) and European Environment Agency (EEA).

There was an existing collaboration between LIFE APEX and European Raptor Biomonitoring Facility COST Action (CA16224) which was mentioned in the ERBFacility Newsletter from April 2021 (to be found in the frame of Highlights on LIFE APEX website). LIFE APEX was presented at

ERBFacility WG3 virtual meeting: The Role of Collections for Contaminant Monitoring in Raptors across Europe – State of Play and Next Steps on 11–12 February 2021. The meeting was set up to inform and inspire natural science collections to engage in pan-European contaminant monitoring.

The aims and objectives of LIFE APEX project were presented at Tox Forum meeting at NiPH, Norway on 12 March 2021 as well as at the Meeting of the Hazardous Substances and Eutrophication Committee (HASEC) / Videoconference on 22–26 March 2021, organised by OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic.

We also cooperate with the EC on the update of the list of contaminants in Descriptors 8 and 9 of the Marine Strategy Framework Directive (MSFD), sharing data with the EC IPCHEM (https://ipchem.jrc.ec.europa.eu/) sharing information with ECHA in support of the Substance Evaluation scheme under REACH legislation. LIFE APEX project was also mentioned in Technical report about IPCHEM by the Joint Research Centre (JRC), the European Commission's science and knowledge service (https://ipchem.jrc.ec.europa.eu/documents/JRC123154_ipchem_2020.pdf).

Wider networking of LIFE APEX is being achieved also through attending relevant conferences and workshops, including those of the Society of Environmental Toxicology and Chemistry SETAC 2019 (https://lifeapex.eu/publications/) (3000–4000) participants at annual meetings (LIFE APEX beneficiaries are well represented as session chairs). The project was well presented at the International Conference on Chemistry and the Environment ICCE 2019 (https://lifeapex.eu/publications/) and ESB 2019. LIFE APEX was also presented at LIFE Platform Meeting on Chemicals on 27-28 November 2019 in Vilnius (Lithuania). Project was also presented by UBA at the EU ECHA PBT expert group in 2020. LIFE APEX was also presented on SETAC Europe Conference SciCon 2020 on 3 – 7 May 2020 (2 Poster presentations) and on SETAC Europe Conference 2021 on 3 – 6 May 2021 (1 Poster presentation) more information is available here: https://lifeapex.eu/publications/. Other submitted publications await official publication.

All of the above was well appreciated by the project's Regulatory Advisory Board (https://lifeapex.eu/rab-members/) who were encouraging the project to deliver the risk assessment methodologies and supporting results as soon as possible in support of European chemicals management policies.

D1.6 Policy briefs in support of regulatory applications REACH and BPR (Lead UBA) Status: Completed

This involved development of a targeted approach to deliver relevant policy messages, identification of key officials in key policy/regulatory stakeholders (DG ENV, DG GROW, JRC, ECHA, EFSA, MSCAs, PBT assessors, etc.) and development of tailored policy briefs for these audiences in relation to specific policy and regulatory processes (e.g., PBT assessment).

The planned and predicted outputs of Action D1 were proceeding according to the LIFE APEX plan. No deviations are identified.

The objective of Action D1 was to develop a project dissemination and communications strategy and to implement the strategy's actions. We set up a dedicated Dissemination and Communications Subgroup of the Project Steering Group (see Action E1) to coordinate dissemination and communications activity and have contracted external specialist communications contractor to support this Action.

The project was in close contact with the European Commission via its services (ECHA, JRC, EFSA), industry, academia and NGOs represented in our Regulatory Advisory Board (RAB – see Action D2). The ICPDR, OSPAR, HELCOM and Black Sea Commission are already using LIFE APEX protocols for sampling and sample analysis within related regional projects.

It is expected that after end of project, relevant dissemination and communication activities developed by LIFE APEX will be continued through the NORMAN platform.

Two policy briefs are a part of this report. The first policy brief ("*Using environmental monitoring data from apex predators for chemicals management: towards better use of monitoring data from apex predators in support of prioritisation and risk assessment of chemicals in Europe*") aims to demonstrate the value of apex predator samples from European sample collections. We shortly mention the regulatory requirements for using monitoring data from apex predators (e.g., open access databases and quality assurance measures) and demonstrate how LIFE APEX responds to these requirements (LIFE APEX Database Systems). Here we also mention the added value of digital sample freezing for future retrospective analysis.

The second policy brief ("*Using environmental monitoring data from apex predators for chemicals management: towards harmonised sampling and processing of archived wildlife samples to increase the regulatory uptake of monitoring data in chemicals management*") is not so much focused on the samples and how to use them but rather on the regulatory use of the data. The policy brief mentions short comings in the current chemicals legislations and how chemical monitoring data from wildlife, in particular from apex predator, can help to prioritize potential hazardous chemicals and frequently occurring chemical mixtures.

The Policy Briefs were published in *Environmental Sciences Europe* (Deliverable D.1.4, Annex 1, Annex 2).

ACTION D2:
Networking with key users to promote regulatory and market uptake of LIFE APEX approaches and outputs

Foreseen start date:	**Q4 2018 (1 October 2018)**
Actual start date:	**Q4 2018 (1 October 2018)**
Foreseen end date:	**Q2 2022 (30 June 2022)**
Actual end date:	**Q2 2022 (30 June 2022)**

SUB-ACTIONS

D2.1 Regulatory Advisory Board (Lead UBA) Status: Completed

We have established a Regulatory Advisory Board (https://lifeapex.eu/rab-members/), with representatives from the regulatory community: relevant EU agencies (ECHA, EFSA); relevant EC Directorates General (ENV, JRC); and MSCAs for REACH, BPR and other chemicals regulations, WFD and MSFD. The Regulatory Advisory Board met annually and advised on the regulatory applications of LIFE APEX (**see document submitted with the Mid-term report on 27/02/2020 -** "Annex 5, Annex 6"), in particular in relation to REACH and BPR, but also other chemicals regulations, WFD and MSFD, with a view to optimising regulatory value of LIFE APEX outputs. The RAB members were regularly informed about project updates and were asked to provide feedback on the outcomes of the project. The RAB meetings were held in June 2019, January 2020 and 14 June 2022.

D2.2 Review of use of environmental monitoring data in chemical risk assessment (Lead UBA) Status: Completed

Institutions involved in chemicals regulations were asked via an online questionnaire for their perspectives and experience in the use of chemical monitoring data from biota. 90% of the respondents stated that they are interested in using such data but more than half lack experience in the field. Detailed information on the evaluation and discussion of results can be found in the document submitted with this report (Annex 6).

D2.3 Development of protocols for regulatory application of approaches and methods of the four Demonstrators (Lead UBA) Status: Completed

This involved working with regulators (including the Regulatory Advisory Board) to develop protocols for regulatory application of the approaches and methods of: Demonstrator 1 for the identification of chemicals in the environment; Demonstrator 2 for prioritisation of substances for hazard (PBT) assessment; Demonstrator 3 for assessment of effectiveness of risk mitigation measures; Demonstrator 4 for the determination of predominant chemicals mixtures (Deliverable D.2.1, Annex 1-Annex 4).

D2.4 Links with relevant policy and regulatory forums (Lead UBA) Status: Completed

We have identified and established early links with relevant EU policy and regulatory forums including relevant expert groups and Member State Committees of ECHA and possibly also of other organisations, e.g., OECD. We were attending and presenting LIFE APEX to these forums and receiving feedback on policy and regulatory relevance of LIFE APEX actions and outputs. Engagements are intensifying now that LIFE APEX B Actions, in particular the four Demonstrators, are starting to produce results. Relevant representatives of these policy and regulatory forums were invited to the LIFE APEX Final conference in Berlin (June 2022).

D2.5 Engaging with industry (Lead UBA) Status: Completed

We prepared a report (Deliverable D.2.2, Annex 1) targeted at the chemicals industry and down-stream users of chemicals, pulling together the relevance of the outputs from the four Demonstrators

to industry and the chemicals value chain. The report was written through a business lens with a view to enhancing impact with business. The report includes the industry relevance, in the EU regulatory context, of the use of AP&P chemical monitoring data for: detection of chemicals in the environment (incorporating results from Demonstrator 1, Tier 1 – Tier 3); prioritisation of chemicals for PBT assessment (incorporating results from Demonstrator 2); assessment of effectiveness of risk mitigation measures (incorporating results from Demonstrator 3 and their application to SEA); and determination of predominant chemical mixtures in the environment (incorporating results from Demonstrator 4). Based on this report, UBA used its extensive links with industry to engage in a dialogue on the relevance of LIFE APEX methods and outputs. This includes links with CEFIC. Industry representatives were also invited to the Final conference in Berlin (June 2022).

The planned and predicted outputs of Action D2 were proceeding according to the LIFE APEX plan. No deviations have been identified.

The objective of Action D2 was to network with key users (regulators, industry) to promote regulatory and market uptake of LIFE APEX approaches and outputs, including harmonized approaches and guidance for sampling, processing, archiving and analysis of AP&P samples, the AP&P Knowledge Base, and the approaches of the four Demonstrators. The Regulatory Advisory Board was established after the second Life APEX project meeting held in January 2019. RAB members were from DG Environment, DG JRC, the European Chemical's Agency (ECHA), European Food Safety Agency (EFSA), NGOs, CEFIC and the national agencies RIVM (NL) and NIVA (NO). RAB members showed great interest in chemical monitoring data from AP&P and provided valuable input on individual compounds detected in the samples as well as substance lists for screening exercises in LIFE APEX. The time schedule for the meetings was once per year. The first meeting took place in summer 2019, the second meeting in January 2020 (**see document submitted with the Mid-term report on 27/02/2020** - "Annex 5, Annex 6") and the third "face to face" meeting took place in Berlin during the LIFE APEX Final Conference in June 2022 (Annex 2). Institutions involved in chemical management were invited to respond to an on-line questionnaire in May 2019. Some of the recipients disseminated the questionnaire in their institution, which resulted in an extended time frame for receiving answers. In consequence, the final report on the questionnaire was delayed. However, this did not affect any other action or milestone. After all answers were submitted, the online questionnaire was evaluated by UBA (Annex 6). The perspective on using chemical monitoring data from biota and especially from apex predators was positive. However, respondents stated a lack of standardized procedures on how to use such data for chemical regulation. This demonstrates the need for establishing guidance on the use of chemical monitoring data as carried out under Sub-actions B5.4 and B5.5. Furthermore, respondents indicated target compounds in which they are particularly interested - this list was used for Actions B4 and B5.

Close cooperation with ECHA, EFSA and EC JRC has been established. The project was organising bilateral discussions with each of the EC services to reflect their particular needs.

Actions A1–A3 developed Key Elements to support and sustain use of AP&P chemical monitoring data and Actions B4–B7 demonstrate novel approaches for use of chemical monitoring data for: (a) detection of chemicals in AP&P; (b) prioritisation of substances for hazard (PBT) assessment; (c) assessment of effectiveness of risk mitigation measures (RMM) taken under REACH and/or BPR and; (d) determining predominant chemicals mixtures. These Actions are oriented to known needs of regulators. At the NORMAN 10th anniversary workshop in Brussels in October 2016, for example, ECHA called for assistance with better use of monitoring data in relation to prioritisation in the determination of PBT compounds, and the EC seeks better use of monitoring data to help assess the effectiveness of European chemicals regulations (see ECHA and DG ENV presentations: https://www.normandata.eu/?q=node/275). Action D2 involved networking with relevant regulators to develop protocols for application of the approaches and methods demonstrated. Action D2 also involved working with industry and down-stream users in the chemicals value chain to explore the

relevance of LIFE APEX outputs to these market players. The four LIFE APEX Demonstrators have substantial relevance for these players.

ACTION E1:
Project management, risk management and administration and After-LIFE Plan

Foreseen start date:	**Q4 2018 (1 October 2018)**
Actual start date:	**Q4 2018 (1 October 2018)**
Foreseen end date:	**Q3 2022 (31 August 2022)**
Actual end date:	**Q3 2022 (31 August 2022)**

SUB-ACTIONS

E1.1 Project Management by EI (Lead EI) Status: Completed

The following LIFE APEX Groups were established:

The LIFE APEX **Project Steering Committee (PSC)**, consisting of 8 members, representing each Beneficiary:

- Jaroslav Slobodnik (EI)
- Natalia Glowacka (EI)
- Gabriele Treu (UBA) – replaced by Jan Koschorreck (UBA)
- Richard Shore (CEH) – replaced by Lee Walker (UKCEH)
- Nikolaos Thomaidis (UoA)
- Rene Dekker (Naturalis)
- Alessandra Cincinelli (UNIFI)
- Heinz Ruedel (Fh-IME) – cancelled due to withdrawal of Fh-IME from LIFE APEX consortium

The LIFE APEX **Project Management Group** (PMG) was consisting of 3 members (**see document submitted with the Mid-term report on 27/02/2020** – "Annex 7"). The LIFE APEX Standing Sub-Groups consisted of 3 internal groups: **Replication and Transfer (R&T) Sub-Group** (4 members), **Dissemination and Communication (D&C) Sub-Group** (6 members) and **Audit and Risk (A&R) Sub-Group** (4 members).

Project Management Personnel

The Coordinating Beneficiary appointed the following Project Management Personnel:

Project Coordinator (>50% time): was responsible for overall supervision of the project including ensuring efficient and timely progress in relation to the Objectives, Actions, Milestones, Deliverables and Reporting schedule.

Project Manager (c. 90% time): was responsible for day-to-day implementation and administration in accordance with LIFE rules. Give relevant experience of the named person.

Financial Manager (50% time): was responsible for coordinating financial implementation, monitoring and reporting in accordance with LIFE rules.

LIFE APEX applied best practice in **green procurement policy** (**see document submitted with the Mid-term report on 27/02/2020 –** "Deliverable E.1.1, Annex 2"), in relation to reimbursement of travel and subsistence expenses for LIFE APEX. LIFE APEX beneficiaries have a range of green procurement policies and guidelines:

UBA has published detailed Guidelines for Sustainable Organisation of Events;

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 is in accordance with the latest EU Procurement Directive 2014/24/EU (as transposed into national procurement legislation). Procurement by private bodies meets at least the same standards.

E1.2 Technical and Financial Reporting (Lead EI) Status: Completed

All Beneficiaries reported quarterly on progress to PSC, in relation to the Actions, Sub-Actions, Milestones and Deliverables for which they are responsible. Draft Technical and Financial Reports were submitted to PSC for approval in advance of submission to EC.

E1.3 Develop and refine an After-LIFE Plan (Lead EI) Status: Completed

Work to develop the After-LIFE Plan started early in the project. The final Plan is submitted with this report (Deliverable E.1.2, Annex 1). It sets out how the dissemination and communication of the results will continue after the end of the project. It gives details regarding what actions will be carried out, when, by whom, and using what sources of finance. The After-LIFE Plan is presented in English, in paper and electronic format. Our After-LIFE Plan focusses on actions including: further sampling and analyses; on-going networking; on-going promotion of harmonised approaches among ESBs and NHMs; on-going maintenance and population of the APEX Knowledge Base; and on-going interactions with regulators to support uptake of the approaches demonstrated by LIFE APEX. A comprehensive Exploitation Plan is included in the After-LIFE Plan.

The planned and predicted outputs of Action E1 were proceeding according to the LIFE APEX plan. No deviations have been identified.

The objective of Action E1 was to ensure robust project management, risk management and administration, for the smooth and timely implementation of the project in accordance with LIFE rules. The top decision-making body was the Project Steering Committee (PSC). Members of the PSC included the Project Coordinator (PSC Chair) and Project Manager (both EI), a representative of each AB, and, where not among the above, leads for each Action. The Steering Committee met 5 times (face-to-face or virtually). Decisions were taken by consensus or, when necessary, by vote, with one vote per Beneficiary (when the vote is split, the Chair has the casting vote).

6.2. Main deviations, problems and corrective actions implemented

No significant deviations or problems have been encountered at the project's implementation. Smaller number of samples in Tier 1 (67 instead of 100) was compensated by increase in number of samples in Tier 2 and Tier 3.
Number of samples (Tier 1 – Tier 3):
Tier 1: planned 100 -> 67 analysed
Tier 2: planned 54 -> 68 analysed
Tier 3: planned 40 -> 63 analysed
There were no major delays and actions were implemented according to the planned budgeted timeline, with slight delays due to the COVID-19 pandemic, which resulted in stricter restrictions regarding the transport of biota samples (dry ice shipments) for Tier 3 analyses by the courier companies. Regarding the B6.3 samples (DEMONSTRATOR 3), 64 samples (Dutch Buzzards) have been analysed for PCBs/PBDEs at the University of Florence, the other remaining samples (UK Buzzards) have been also analysed: 72 samples – SGARs analyses + other 72 samples – mercury analyses. In total we analysed 64 + 72 + 72 = 208 B6.3 samples (instead of the foreseen 144 samples as foreseen in the Grant Agreement). There was no impact on the project budget.
There were two changes in the LIFE APEX consortium. Associated beneficiary UK Centre for Ecology & Hydrology (CEH) that previously operated as part of the Natural Environment Research Council has changed legal status from non-departmental public body to 'not for profit charity' starting from 1 December 2019. The Associated Beneficiary Institute for Molecular Biology and Applied Ecology IME (Fraunhofer IME) left the LIFE APEX consortium in November 2019. Fraunhofer IME has committed itself to support LIFE APEX consortium with all tasks originally intended for their institution, on their own expenses, without the requirement for financial contribution from the project consortium. Their duties were taken over by Environmental Institute (EI) with the support of Fraunhofer IME. Their expertise supported LIFE APEX project especially in Actions B.4 and B.5. We ensured that implementation of LIFE APEX project proceeded in line with agreed arrangements (project actions, deliverables and milestones). The scope and objectives of the project were not altered. LIFE APEX Associated Beneficiaries had the professional and technical capacity to implement all tasks as planned in the Grant Agreement.

6.3. Evaluation of Project Implementation

Action	Foreseen in the revised proposal	Achieved	Evaluation Date of completion
ACTION B1: KEY ELEMENT 1: Engaging key Replication and Transfer (R&T) Partners, assessing R&T Partners' resources and capacities for AP&P chemicals monitoring and developing an R&T Plan	**Objectives:** (1) to identify, and secure engagement of, relevant R&T Partners; (2) to assess R&T Partners' resources and capacities for AP&P chemicals monitoring; (3) to develop an R&T Plan; (4) to provide general support to ongoing R&T engagement. **Expected results:** Inventory of ESBs, NHMs and other collections involved in collecting AP&P samples	✓ Deliverable B.1.1 - List of potential R&T Partners and areas of interest. ✓ Deliverable B.1.2 - R&T Plan. ✓ Deliverable B.1.3 - R&T Partner resources & capacities questionnaire responses. ✓ Deliverable B.1.4 - Updated R&T Plan. ✓ Deliverable B.1.5 - Updated R&T Plan. ✓ Deliverable B.1.6 - Updated R&T Plan.	30 September 2018 28 February 2019 31 August 2019 31 August 2019 31 August 2020 31 August 2021
ACTION B2: KEY ELEMENT 2:	**Objectives:** (1) to review and harmonise quality	✓ Deliverable B.2.1 - Guidance document for	31 August 2019

Reviewing and harmonizing quality assurance (QA) for AP&P sampling, sample processing and archiving and for their chemical analysis	assurance (QA) criteria, measures and protocols for AP&P sampling, sample processing and archiving by both ESBs and NHMs; (2) to develop guidance for the analysis (targeted analysis, non-target screening analysis) of contaminants in these samples; (3) to develop guidance for users to assess the quality of AP&P chemical monitoring data. **Expected results:** Review and guidance documents on QA criteria, measures and protocols for sampling, processing and archiving of AP&P samples, analysis of chemical contaminants in AP&P, and assessing quality of AP&P contaminant data	chemical analysis of environmental contaminants in AP&P samples. ✓ Deliverable B.2.2 - Guidance document for sampling, processing, archiving samples. ✓ Deliverable B.2.3 - Guidance document on assessing quality of AP&P contaminants data.	31 August 2020 31 August 2021
ACTION B3: KEY ELEMENT 3: Enhancing access to relevant AP&P samples and related contaminant data, and enhancing compatibility and interoperability of data, through an APEX Knowledge Base	**Objectives:** (1) to develop a European 'AP&P Knowledge Base' to enhance access to AP&P samples and to contaminant data in AP&P samples. This involved developing a web-based, open access database, with three linked modules: – Module 1: APEX Samples Database – data on available AP&P samples and sampling programmes; – Module 2: APEX Target Analyses Database – data from targeted analyses of AP&P samples; – Module 3: APEX Non-target Screening (NTS) Analyses Database – data from NTS analyses of AP&P samples. **Expected results:** A European database, well populated with data from across Europe, with three modules: (a) samples module with samples data from at least 75 ESBs/NHMs; (b) target analyses data module; (c) non-target screening data module [(b) and (c) together containing >1 data million entries]	✓ Deliverable B.3.1 - APEX Samples Database (Module 1) and DCT. ✓ Deliverable B.3.2 - APEX Target Analyses Database (Module 2) and DCT. ✓ Deliverable B.3.3 - APEX Non-target Screening (NTS) Analyses Database (Module 3) and DCT.	31 December 2018 30 September 2019 31 October 2019
ACTION B4: DEMONSTRATOR 1: Revealing presence of chemical contaminants in AP&P samples through target and non-target screening (NTS) analyses	**Objectives:** (1) to demonstrate how state-of-the-art chemical screening can be used to detect presence of wide-scope chemicals in AP&P samples. **Expected results:** Data from targeted and NTS analyses of 100 Tier 1 samples; Data from targeted and NTS analyses of 54 Tier 2 samples; Data from targeted and NTS analyses of up to 40 Tier 3 Samples; Report on methodologies used and overview of data obtained by Tier 1 (wide-scope screening), Tier 2 (time trend analysis) and Tier 3 (replication)	✓ Deliverable B.4.1 - Data from targeted and NTS analyses of 100 Tier 1 samples available in APEX KnowledgeBase. ✓ Deliverable B.4.2 - Data from targeted and NTS analyses of 54 Tier 2 samples available in APEX KnowledgeBase. ✓ Deliverable B.4.3 - Data from targeted and NTS analyses of up to 40 Tier 3 Samples available in APEX KnowledgeBase. ✓ Deliverable B.4.4 - Report on methodologies used and overview of data	31 August 2019 30 June 2020 30 June 2021 28 February 2022

		obtained by Tier 1 (wide-scope screening), Tier 2 (time trend analysis) and Tier 3 (replication).	
ACTION B5: DEMONSTRATOR 2: Prioritisation of the most relevant contaminants in AP&P samples and assessment of the applicability of such monitoring data for PBT assessment in the European regulatory context	**Objectives:** (1) to demonstrate how wide-scope chemical screening data can be prioritised to select the most relevant substances for development of further hazard (PBT) assessment under REACH and BPR. **Expected results:** List of top 300 contaminants in AP&P samples, guidance document for assessment of PBT properties of contaminants in AP&P samples	✓ Deliverable B.5.1 - List of top prioritised 300 AP&P pollutants and associated PBT assessments. ✓ Deliverable B.5.2 - A draft guideline for assessment of PBT properties of pollutants in AP&P samples. ✓ Deliverable B.5.3 - A substance evaluation for 1 – 2 substances using monitoring data for the B-criterion.	30 November 2021 28 February 2022 28 February 2022
ACTION B6: DEMONSTRATOR 3: Demonstrating use of raptor chemical monitoring data to assess impact and effectiveness of risk mitigation measures at national and European scales	**Objectives:** (1) to show that chemical monitoring data from raptor samples from ESBs and NHMs can be used for wide-scale assessment of chemical risk mitigation measures (RMM); (2) to identify key issues in using ESB samples, show that NHM samples can usefully complement ESB samples and develop guidelines for tracking changes in chemical concentrations in AP&P samples, taking into account sample pooling (to ensure monitoring is cost-effective, tractable and affordable) and scalability (national to pan-European). **Expected results:** Guidelines and framework for monitoring terrestrial pollutants to assess success of pan-European mitigation actions; Publications on B6 approach	✓ Deliverable B.6.1 - Guidelines for use of raptor species to monitor changes in terrestrial pollutants. ✓ Deliverable B.6.2 - A framework for monitoring terrestrial pollutants to assess the success of pan-European mitigation actions. ✓ Deliverable B.6.3 - Two peer-reviewed papers on B6 approach, method and findings submitted for publication.	31 August 2019 28 February 2022 28 February 2022
ACTION B7: DEMONSTRATOR 4: Defining predominant chemical mixtures in AP&P samples	**Objectives:** (1) to demonstrate how data obtained from national and Europe-wide screening campaigns can be used to identify predominant chemical mixtures of concern. **Expected results:** List of predominant mixtures in AP&P samples	✓ Deliverable B.7.1 - List of predominant chemical mixtures in AP&P samples.	28 February 2022
ACTION C1: Monitoring the impact of the project actions in relation to the specified performance indicators	**Objectives:** (1) to monitor outputs and impacts of the action in relation to selected LIFE Performance Indicators and LIFE APEX Project Specific Indicators. **Expected results:** Project technical and financial reports, performance reports (in relation to performance indicators)	✓ Deliverable C.1.1 - List of project performance indicators. ✓ Deliverable C.1.2 - Project Baseline Report. ✓ Deliverable C.1.3 - Ex post impact assessment. ✓ Deliverable C.1.4 - Socio-economic impact assessment. PROJECT REPORTS (Deliverables): ✓ Deliverable - Mid-term	30 November 2018 30 November 2018 31 August 2022 31 August 2022 28 February 2020

		Monitoring Report on LIFE Performance Indicators (KPIs). ✓ Deliverable - Progress Monitoring Report on LIFE Performance Indicators (KPIs). ✓ Deliverable - Final Monitoring Report on LIFE Performance Indicators (KPIs).	30 June 2021 30 November 2022
ACTION D1: Development of general dissemination and communications strategy and implementation of the strategy's actions	**Objectives:** (1) to develop a project dissemination and communications strategy and to implement the strategy's actions. **Expected results:** Project website, video, at least 4 peer-reviewed publications of key methods and applications	✓ Deliverable D.1.1 - Notice board at each Beneficiary's office. ✓ Deliverable D.1.2 - Layman's brochure/flyer. ✓ Deliverable D.1.3 - Project website. ✓ Deliverable D.1.4 - 2 policy briefs published. ✓ Deliverable D.1.5 - Layman's report.	30 November 2018 30 November 2018 30 November 2018 28 February 2022 28 February 2022
ACTION D2: Networking with key users to promote regulatory and market uptake of LIFE APEX approaches and outputs	**Objectives:** (1) to network with key users (regulators, industry) to promote regulatory and market uptake of LIFE APEX approaches and outputs, including harmonized approaches and guidance for sampling, processing, archiving and analysis of AP&P samples, the AP&P Knowledge Base, and the approaches of the four Demonstrators. **Expected results:** Protocols for regulatory applications, take-up by ECHA and Member State Competent Authorities	✓ Deliverable D.2.1 - Protocols for regulatory application of novel approaches. ✓ Deliverable D.2.2 - Report for chemicals producers and users.	30 April 2022 30 April 2022
ACTION E1: Project management, risk management and administration and After-LIFE Plan	**Objectives:** (1) to ensure robust project management, risk management and administration, for the smooth and timely implementation of the project in accordance with LIFE rules. **Expected results:** After-LIFE Plan	✓ Deliverable E.1.1 - Project policy on, and specific mechanisms for, green procurement. ✓ Deliverable E.1.2 – After-LIFE Plan.	30 November 2018 30 November 2022

The immediately visible project results were:

- Project website;
- The AP&P Knowledgebase, each populated with data from emerging results, with three modules: (a) samples module; (b) target analyses data module; (c) non-target screening data module;
- Guidance documents on QA criteria, measures and protocols for sampling, processing and archiving of AP&P samples, analysis of chemical contaminants in AP&P, and assessing quality of AP&P contaminant data;
- Guidelines and framework for monitoring terrestrial pollutants to assess success of pan-European mitigation actions.

Further project results were:

- Inventory of ESBs, NHMs and other collections involved in collecting AP&P samples;

- List of chemicals in AP&P samples;
- List of predominant mixtures in AP&P samples;
- List of top 300 contaminants in AP&P samples, guidance document for assessment of PBT properties of contaminants in AP&P samples;
- Protocols for regulatory applications, take-up by ECHA and Member State Competent Authorities;
- Project technical and financial reports, performance reports (in relation to performance indicators), audit reports;
- Video, 4 peer-reviewed publications of key methods and applications;
- After-LIFE Plan.

LIFE APEX involved a transnational approach, with beneficiaries from six countries with good geographical balance across Europe. Moreover, LIFE APEX involved engagement of R&T partners from most other EU MS. There is clear EU added value of this transnational approach because; (a) it brings together some of the best available expertise and top infrastructures (ESB, NHM, lab) 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. LIFE APEX took up relevant knowledge from EU research projects, notably the NORMAN Network, whose early development was funded under FP6. LIFE APEX benefits from NORMAN's work on NTS and integrates the planned AP&P KnowledgeBase with the NORMAN EMPODAT and DSFP databases. The NORMAN Network is financially self-sustaining and this integration offers strong sustainability to the AP&P Knowledgebase.

6.4. Analysis of benefits

The project was implemented largely according to the plan and there were no significant deviations from the targets set initially were anticipated (cf. 6.3 above).

Qualitative environmental benefits

The project outputs will bring better use of chemical monitoring data, in order to (a) detect which chemicals are present in the environment, (b) determine which mixtures predominate in the environment, (c) prioritise substances for hazard assessment and (d) assess effectiveness of RMM. Outputs should help 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 and thereby protecting human health and the environment. These impacts are clear in that the mechanism for environmental impact – that is, more efficient prioritisation of hazardous substances, and improved knowledge of efficacy of RMM – leading to reduced exposure of humans and wildlife to harmful substances, is clear. The impacts are potentially substantial, in that the approaches and methods demonstrated can impact on any of the many tens of thousands of substances that fall under REACH and/or BPR. The impacts are ambitious, in that LIFE APEX aimed 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 developed to support and sustain regulatory take-up, are based on tried and tested analytical methods; (b) the Beneficiaries had 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 was a strong support for the project from ECHA, regulators, ESBs and NHMs.

LIFE APEX contributed also to the objectives of the Birds and Habitats 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.

Economic and social benefits
The significant economic benefits are expected in a long-term 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.
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. 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 plant protection products (PPP), medicinal products and/or persistent organic pollutants (POPs) regulations; and reduced exposure of threatened and protected species to harmful substances in the environment.

Replicability, transferability, cooperation
We will ensure that lessons learnt from LIFE APEX are translated into real environmental improvements – in terms of reduced exposure of humans and wildlife to harmful chemicals – through our R&T Strategy and related actions. Our R&T strategy had a strong focus on engaging regulators to support uptake of LIFE APEX's novel approaches and methods for the systematic use of contaminant data from AP&P in chemicals management – in particular in relation to REACH and the Biocides Regulation. This included in particular engagement of ECHA and national competent authorities (NCAs) through the ECHA PBT Expert Group. This uptake was delivered through R&T activities specified in Actions B1, B2, B3, C1, D2 and E1. The vision of our replicability and transferability (R&T) strategy is a European community of regulators, sample collections (ESBs, NHMs and others) and analytical laboratories working together to apply reliable chemical monitoring data from AP&P for better chemicals management to protect human health and the environment. The aim of our R&T strategy was to engage regulators, ESBs, NHMs and other collections, and analytical laboratories, from at least 60% of EU Member States, in LIFE APEX R&T activities. The purpose of our R&T strategy was:

- to support transfer and replication of LIFE APEX's novel approaches and methods for the systematic use of contaminant data from AP&P in chemicals management, from the institutions and countries of our beneficiaries to and by key institutions and countries elsewhere in the EU, in order to develop a critical mass of uptake;
- to secure the necessary samples for our Demonstrator actions and to populate the planned AP&P KnowledgeBase with data (on AP&P samples and sampling programmes, AP&P chemical monitoring data), not only from the institutions and countries of our beneficiaries, but also from key institutions and countries elsewhere in the EU.

Best practice lessons
The project built on the state-of-the-art methodologies and practices in collection, storage and analysis of biota samples. Additionally, the latest advances in archiving data in open access on-line database system and risk assessment of the obtained data are being implemented with direct involvement of one of the key European environmental regulators (UBA) in close cooperation with the EU services dealing with the chemicals management and industry. A possibility to derive P, B and T properties for all tested chemicals (>66,000; UBA using JANUS modelling tool for assessment of REACH chemicals) appeared during the project implementation and will be used to prioritise chemicals detected in AP&P samples more efficiently.

Innovation and demonstration value
With high probability, many of the pollutants and their metabolites found in top predators are present also in humans. The entire chain of processes applied in the project from sample collection to assessment of the results and communicating the risks of chemicals in top predators to regulators at the national and EU level is entirely innovative. It is expected that if successfully demonstrated (cf. four Demonstrators above) the approach will be promoted by the EC and followed Europe-wide by MSCAs.

Policy implications
The long-term goal of LIFE APEX is to reduce human and wildlife exposure to harmful chemicals in the environment. LIFE APEX aimed to contribute to this goal by responding to needs of regulators (ECHA, Member State Competent Authorities) in relation to the use of chemical monitoring data. The short-term aim of the project is to improve systematic use, by regulators, of chemical monitoring data from apex predators and prey ('AP&P') for better chemicals management, thereby reducing exposure to harmful substances and protecting human health and the environment. Two LIFE APEX policy briefs were published (cf. Technical part / Deliverable D.1.4, Annex 1 and Annex 2).

7. Key Project-level Indicators

The **LIFE KPIs** set for LIFE APEX are given in the online KPI module (Annex 7), including related baseline values, target values for end of project and forecast values for 5 years beyond end of project.

The **Project-Specific Indicators** set for LIFE APEX at end of project are shown in the table below.

No.	Indicator	Estimated impact		Comment
		absolute values	% values	
1	Number of ESBs, NHMs and other collections and labs engaging in LIFE APEX.	10 ESBS, 15 NHMs, 5 Labs	n/a	Baseline = 0
2	Number of data entries made available and accessible in each of the three modules of the AP&P Knowledge Base.	> 5,000 data entries in APEX Samples Database; >410,000 data entries in APEX Target Analyses Database; >600,000 data entries in APEX Non-target Screening (NTS) Analyses Database	n/a	Baseline = 0
3	Degree of comparability and interoperability of the data in the AP&P Knowledge Base.	Full comparability and interoperability of the data based on harmonised Data Collection Templates	n/a	Baseline = 0
4	Frequency of use of the database by regulators.	50 consultations per month	n/a	Baseline = 0
5	Number of chemicals identified through Demonstrator 1 as present in the AP&Ps.	>1,000	n/a	Baseline = 0
6	Number of substances prioritised through Demonstrator 2 for hazard assessment.	300	n/a	Baseline = 0
7	Power and cost-effectiveness of Demonstrator 3 approach to detect changing environmental contamination following risk management measures	Approach shown to be viable in terms of power and cost-effectiveness	n/a	Baseline = 0
8	Extent of new information provided through Demonstrator 4 on predominant chemicals mixtures in AP&Ps.	A list of predominant chemicals mixtures in all AP&P samples and per biota specie	n/a	Baseline = 0
9	Extent of uptake by R&T Partners of guidelines for sampling, processing and archiving of AP&P samples.	10 ESBs, 15 NHMs	n/a	Baseline = 0
10	Extent of uptake by R&T Partners of guidelines for analyses of AP&P samples.	10 labs	n/a	Baseline = 0
11	Extent of uptake, by regulators, of the Demonstrator 1 approach for detection of contaminants and predominant mixtures in the environment;	Data accessible via link with IPCHEM (DG ENV, JRC data platform); ECHA, UBA using actively the database in its testing phase	n/a	Baseline = 0
12	Extent of uptake, by regulators, of the Demonstrator 2 approach for prioritisation of substances for hazard assessment, and better accounting in hazard assessment for environmental presence of substances;	Prioritisation methodology used by UBA and ECHA and shared with other MS	n/a	Baseline = 0
13	Extent of uptake, by regulators, of the Demonstrator 3 approach for assessment of effectiveness of risk mitigation measures.	Framwork accepted by ECHA as pertinent to assessment of effectiveness of RMM	n/a	Baseline = 0
14	Extent of uptake, by regulators, of the Demonstrator 4 approach to determination of predominant chemical mixtures.	Optimised statistical tools used by UBA and ECHA and shared with other MS	n/a	Baseline = 0

These indicators and their related baselines were approved by the Consortium at the Kick-off meeting. Progress against these 14 indicators is summarised below:

1. **Indicator 1**: Number of ESBs, NHMs and other collections and labs engaging in LIFE APEX.
   Progress by EOP (End of project): The following numbers of collections (inclusive of LIFE APEX partners UKCEH and Naturalis Biodiversity Center) actively engaged in LIFE APEX through supply of samples and as prospective co-authors of resulting papers:
   - Marine mammals: Demonstrator 1 Tier 1 – 4; Tier 2 – 1; Tier 3 – 10;
   - Otters: Demonstrator 1 Tier 1 – 4; Tier 2 – 1; Tier 3 – 8;
   - Raptors: Demonstrator 1 Tier 1 – 1; Tier 2 – 1; Tier 3 – 13;
   - Fish: Demonstrator 1 Tier 1 – 4; Tier 2 – 1; Tier 3 – 0;
   - Other taxa: Demonstrator 1 Tier 1 – 1; Tier 2 – 0; Tier 3 – 1;
   - Raptors: Demonstrator 3 Action B6.3 – 2 collections; Action B6.4 - 18 collections.

   LIFE APEX has engaged with 50+ individuals in natural science collections (ESBs & NHMs) across Europe as suppliers of samples and as co-authors for resulting papers. LIFE APEX analyses have involved 5 labs (UoA, EI, UKCEH, UNIFI, Fh-IME). We anticipate 50+ representatives from at least 12 ESBs, 25 NHMs and 15 labs to be involved by 5 years after EOP. More detailed information is provided in "Report on Ex-post impact assessment and Socio-economic impact assessment".
   In addition, representatives from well over 100 collections and labs engaged in LIFE APEX events including the Final Workshop (Berlin hybrid event) and a collaborative virtual event convened with the European Raptor Biomonitoring Facility COST Action in February 2021 on The Role of Collections for Contaminant Monitoring in Raptors across Europe.

2. **Indicator 2**: Number of data entries made available and accessible in each of the three modules of the AP&P Knowledge Base.
   Progress by EOP: 104 sample collections are shown in the LIFE APEX Samples Catalogue representing >200,000 individual samples from 20 species in 24+ countries (https://www.norman-network.com/apex/catalogue/); 953,444 data entries on 3253 substances are shown in the APEX Target Analyses Database (https://www.norman-network.com/apex/lacod/); >13 million data entries are shown in the APEX Non-target Screening (NTS) Analyses Database (https://norman-data.net/Verification/).

3. **Indicator 3**: Degree of comparability and interoperability of the data in the AP&P Knowledge Base.
   Progress by EOP: Harmonised DCTs have been prepared and used giving full comparability and interoperability of the data.

4. **Indicator 4**: Frequency of use of the database by regulators.
   Progress by EOP: The LIFE APEX Chemical Occurrence Database accessed by regulators c. 1,200 times during the last two years of the project (c. 50 times per month). DSFP used for regulatory purposes (ECHA PBT Expert Group, UBA Germany, UBA Austria; search for a contaminants or group of contaminants of potential concern in biota samples) c. 15 times. More detailed information is provided in "Report on Ex-post impact assessment and Socio-economic impact assessment".

5. **Indicator 5**: Number of chemicals identified through Demonstrator 1 as present in the AP&Ps.
   Progress by EOP:

Tier 1 analyses (67 samples from UK, DE, NL, SE, DK):

- NTS (suspect screening of >66,000 substances) (at UoA) – >4000 substances detected including industrial chemicals, pharmaceuticals, personal care products, plant protection products, surfactants, and per- and polyfluoroalkyl substances (PFAS),
- Wide-scope target analyses (at UoA) – 121 CECs detected including pharmaceuticals, personal care products, plant protection products, surfactants, and per- and polyfluoroalkyl substances (PFAS),
- Conventional target analyses (at EI, UNIFI) – 72 legacy contaminants detected including dioxins and dioxin-like compounds, organophosphate flame retardants (OPFRs), dechlorane plus, chlorinated alkanes, HCB, PCBs and PBDEs.

Tier 2 analyses (68 samples, time-trend analyses):

- NTS (suspect screening of >66,000 substances) – >4000 substances detected (same classes as for Tier 1),
- Wide-scope target analyses - 84 CECs detected (same classes as for Tier 1),
- Conventional target analyses – 53 legacy contaminants detected (same classes as for Tier 1).

Tier 3 analyses (63 samples from R&T countries):

- NTS (suspect screening of >65.000 substances) – >4000 substances detected (same classes as for Tier 1),
- Wide-scope target analyses - 109 CECs detected (same classes as for Tier 1),
- Conventional target analyses – 51 legacy contaminants detected (same classes as for Tier 1).

6. **Indicator 6**: Number of substances prioritised through Demonstrator 2 for hazard assessment.
   Progress by EOP: Demonstrator 2 has carried out an initial ranking of chemicals detected in AP&P through Demonstrator 1. This ranking has been done for emerging substances based on targeted monitoring and unambiguously identified substances based on suspect target screening results (in total 5009 chemicals of which 818 REACH compounds that are potential CECs. Ranking has been based at this stage on Frequency of Appearance (FoA) and PBT properties of each detected substance, which were derived using the JANUS tool. The ranked substances were manually screened using PBT screening criteria (according to REACH Annex XIII) to determine substances that might be considered a priority for exposure, hazard and risk assessment, yielding a list of 26 top PBT chemicals which may need further management. Furthermore, LIFE APEX identified 24 chemicals for which the exposure assessment needs to be reassessed (e.g. compounds used only as intermediates but frequently occurring in top predators) and 19 substances which potentially poses a quantitative risk (environmental concentration exceeds the effect concentrations).

7. **Indicator 7**: Power and cost-effectiveness of Demonstrator 3 approach to detect changing environmental contamination following risk management measures.
   Progress by EOP: Analysis of the Demonstrator 3 Country-scale study, involving analysis for PCBs and PBDEs in 64 buzzard liver samples collected in Netherlands, and for Hg and SGARs in 72 buzzard liver samples in UK, over the period 1996-2021, found that sufficient power (>70%) can be achieved with relatively few pooled samples to detect small (5-10%) annual changes in average residue magnitude. However, where sample supply and analytical

resources allow, maintaining a higher number of samples per year increases the power to detect change. Pooling samples reduces the number of samples to be analysed, and therefore can be a cost-effective approach for the detection of temporal trends or differences among populations at large spatial scales. By reducing the number of samples to be analysed per time period or per spatial area, pooling may allow monitoring resources to be extended to assessment of contaminant residue levels over longer time periods or larger spatial areas.

8. **Indicator 8**: Extent of new information provided through Demonstrator 4 on predominant chemicals mixtures in AP&Ps.
   Progress by EOP: A battery of complementary statistics and visualization tools have been proposed to determine which chemicals appear in samples together as 'typical mixtures'. An interactive visualization interface has been created to show the spatial distribution of mixtures of contaminants in AP&P samples (https://norman-data.eu/LIFE_APEX2/). Moreover, an application to visualize the co-occurring substances using graph analytics was developed (https://norman-data.eu/LIFE_APEX_Mixtures/). Both tools are hosted in the LIFE APEX database (https://www.norman-network.com/apex/lacod/ - MAPS). These applications will help in the dissemination of LIFE APEX results to scientists, regulators and the public. The final list of predominant mixtures frequently detected in AP&P samples are described in the respective deliverable of LIFE APEX. Moreover, the predominant mixtures will be contributed to the NORMAN Database System – Suspect List Exchange module (https://www.norman-network.com/nds/SLE/).

9. **Indicator 9**: Extent of uptake by R&T Partners of guidelines for sampling, processing and archiving of AP&P samples.
   Progress by EOP: Guidelines have been developed and tested by the project Beneficiaries and circulated to R&T Partners in advance of shipment of samples.

10. **Indicator 10**: Extent of uptake by R&T Partners of guidelines for analyses of AP&P samples.
    Progress by EOP: Guidelines have been developed and tested by the project Beneficiaries.

11. **Indicator 11**: Extent of uptake, by regulators, of the Demonstrator 1 approach for detection of contaminants and predominant mixtures in the environment.
    Progress by EOP: The results have been taken up by regulators especially in terms of design of future regulatory monitoring studies (minimum requirements for pooling and spatial distribution of samples; see Indicator 7). LIFE APEX data from Demonstrator 1 has already supported ongoing risk management measures (e.g. restriction of PFAS and bisphenols in 2022). The LIFE APEX Regulatory Advisory Board indicated strong regulator interest in the approach. The approach has also attracted interest through the ECHA PBT Expert Group and has been taken up by OSPAR and HELCOM. More recently, LIFE APEX approaches are being considered for implementation by the Horizon Europe Partnership for the Assessment of Risk from Chemicals (PARC).

12. **Indicator 12**: Extent of uptake, by regulators, of the Demonstrator 2 approach for prioritisation of substances for hazard assessment, and better accounting in hazard assessment for environmental presence of substances.
    Progress by EOP: Prioritisation (see Indicator 6) has been performed by UBA (the Competent Authority for REACH in Germany). The results were presented to the European Commission and regulators at the project's final workshop in Berlin in June 2022.

13. **Indicator 13**: Extent of uptake, by regulators, of the Demonstrator 3 approach for assessment of effectiveness of risk mitigation measures.
    Progress by EOP: A key opportunity to accelerate uptake of Demonstrator 3 approaches is provided by the recently launched European Partnership for the Assessment of Risks from Chemicals (PARC). Close liaison between monitoring Work Package leads for PARC and LIFE APEX, along with involvement in PARC of LIFE APEX partners (EI, UBA, NKUA and UKCEH) in the PARC project, mean that approaches for RMM assessment demonstrated in LIFE APEX are likely to be considered for inclusion in both design and initiation of monitoring frameworks and extension of monitoring programmes at a pan-European scale. At a country-scale, for example, a 25-year contaminant monitoring programme is being developed over the next 35 years in the UK, with LIFE APEX approaches being strongly considered for inclusion in this programme. Currently base-line contaminant data is being generated using buzzard livers; this data will then be used to inform monitoring design for the next two decades.

14. **Indicator 14**: Extent of uptake, by regulators, of the Demonstrator 4 approach to determination of predominant chemical mixtures.
    Progress by EOP: The co-occurrence application was developed and deployed to the LIFE APEX database. It was used to identify the predominant chemical mixtures in freshwater and marine ecosystems. It identified PFAS, BDE, and PCB to be members of the dominant chemicals for both environments. 4-formylaminoantipyrine and gabapentin-lactam were two prominent chemicals of the chemical mixtures in both environments (freshwater and marine). Important members of the chemical mixtures in the marine environment were the pharmaceutical mexiletine, the surfactant N,N-Bis(2-hydroxyethyl)dodecanamide, the synthetic musk galaxolide, the pesticide isoprocarb and the metabolite of nicotine (nornicotine). The methodology as well as these substances was communicated to regulators.

8. List of annexes

Annex 1 - Questionnaire for sampling, processing, archiving samples
Annex 2 - Agenda of the Final Conference
Annex 3 - Module 1 - DCT for LIFE APEX Sample Catalogue
Annex 4 - Module 2 - DCT for biota for LIFE APEX Chemical Occurrence Data
Annex 5 - Module 3 - DCT for DSFP
Annex 6 - D2 Evalutation Questionaire
Annex 7 - Updated entries from online KPI database
Annex 8 - Supporting documents required in the letter CINEA D.2/MM/D(2022) 5889844 from 25/07/2022
Annex 9 - Supporting documents required in the letter CINEA D.2/MM/D(2021) 4882986 from 02/07/2021
Annex 10 - Minutes of the Project Steering Committee (PSC) Meeting 3
Annex 11 - Minutes of the Project Steering Committee (PSC) Meeting 4
Annex 12 - Minutes of the Project Steering Committee (PSC) Meeting 5
Annex 13 - Document on the VAT exemption (CEH/UKCEH)
Annex 14 - UKCEH supporting documents

9. List of deliverables

Deliverable B.1.5 - Updated R&T Plan
Deliverable B.1.6 - Updated R&T Plan
Deliverable B.2.2 - Guidance document for sampling, processing, archiving samples
Deliverable B.2.3 - Guidance document on assessing quality of AP&P contaminants data
Deliverable B.4.2 - Data from targeted and NTS analyses of 54 Tier 2 samples available in APEX KnowledgeBase
Deliverable B.4.3 - Data from targeted and NTS analyses of up to 40 Tier 3 Samples available in APEX KnowledgeBase
Deliverable B.4.4 - Report on methodologies used and overview of data obtained by Tier 1 (wide-scope screening), Tier 2 (time trend analysis) and Tier 3 (replication)
Deliverable B.5.1 - List of top prioritised 300 AP&P pollutants and associated PBT assessments
Deliverable B.5.2 - A draft guideline for assessment of PBT properties of pollutants in AP&P samples
Deliverable B.5.3 - A substance evaluation for 1 – 2 substances using monitoring data for the B-criterion
Deliverable B.6.2 - A framework for monitoring terrestrial pollutants to assess the success of pan-European mitigation actions
Deliverable B.6.3 - Two peer-reviewed papers on B6 approach, method and findings submitted for publication
Deliverable B.7.1 - List of predominant chemical mixtures in AP&P samples
Deliverable C.1.3 - Ex post impact assessment

Deliverable C.1.4 - Socio-economic impact assessment
Deliverable D.1.4 - 2 policy briefs published
Deliverable D.1.5 - Layman's report
Deliverable D.2.1 - Protocols for regulatory application of novel approaches
Deliverable D.2.2 - Report for chemicals producers and users
Deliverable E.1.2 - After-LIFE Plan