LIFE + Environment Policy and Governance

TECHNICAL APPLICATION FORMS

Part B – Objectives and expected results

SUMMARY DESCRIPTION OF THE PROJECT (Max. 3 pages; to be completed in English)

Project title: PVCFREEBLOODBAG - Public healthcare and plastics makers demonstrate how to remove barriers to PVC-free blood bags in the spirit of REACH

Project objectives:
The **first project objective** is to demonstrate that public healthcare organisations and private plastics manufacturers can cooperate in removing barriers to a PVC-free blood bag. This innovative policy approach is a response to the spirit of the REACH Regulation. Article 1 specifies that its aim is a high level of protection for human health and the environment; manufacturers and downstream users should introduce substances to the market that do not adversely affect human health. Its provisions are based on the precautionary principle.

PVC blood bags require use of the DEHP plasticiser. DEHP is listed as a Substance of Very High Concern in Reach. The major issue that life-saving blood transfusions must be exposed to DEHP is a troublesome fact. For blood bags intended for red blood cells, there are currently no acceptable PVC/DEHP-free alternatives. Suitable materials for PVC-free blood bags exist, but the bags are not being developed. Thus substitution of PVC blood bags is an absolute must. Some 16 million blood bags affect 10 million people in the EU every year.

The first barrier will be overcome through production of an innovative PVC-free blood bag that is of high enough quality for CE marking. The project shall demonstrate a technically and economically feasible alternative to current blood bags, which are made of PVC plastics with DEHP plasticiser. The quality of the prototype blood bag will be verified in two ways. It will be tested to ensure it is suitable for blood storage and for its practicality for hospital use.

The second barrier is the need to verify customer demand for the product, to convince plastics manufacturers of an innovative PVC-free blood bag's market potential, particularly in the EU. This demonstrates a method of verifying stakeholder demand for an improved environmental solution, as well as continuing the efforts of Swedish downstream users at a European level.

The **second objective** is a fall-back alternative. If the innovative PVC-free blood bags prove to be too expensive for general use, they will be proposed for use with vulnerable groups. These include pregnant women, premature babies and people with chronic disease. The biggest use for these groups is for haemodialysis. In the EU there are some 150,000 people that depend on very frequent dialysis.

The **third objective** is to offer a material that manufacturers can use to replace PVC in other blood contact applications as well as in other medical applications. Blood bags are the medical sector's most technically demanding use of PVC/DEHP. Such applications may use 10 times more PVC, than what is used for blood bags.

A **fourth objective** is to offer the new material for food industry applications. In spite of some substitution, the main source of exposure of DEHP/PVC to the human population is dietary. Food contains DEHP derived from environmental contamination and bioaccumulation along the food chain and from leaching during manufacturing, packaging and storing. These applications also represent more than 10 times the use of PVC for bloodbags

Actions and means involved:
The project demonstrates how public and private bodies can work together to create innovative environmental solutions. The Jegrelius Institute for Applied Green Chemistry (Jegrelius) is currently hosted by Region Jämtland (RJ). Jämtland County Council is a major healthcare provider in northern Sweden. In 2010, Jegrelius presented a market study: Technology Procurement of PVC-Free Blood bags. That was one result of a Swedish project with healthcare providers to find a substitute for PVC blood bags. This proposal is a practical response to the limited interest of major producers in providing such blood bags.

Swedish healthcare bodies have initiated this cooperation. A supply chain of specialised companies with unique expertise has been created; it is necessary to work with companies in

three countries outside Sweden to obtain the best supply chain. The number of actions is thus considerable, so some actions have been grouped in the description below.

Project actions are designed to remove two barriers to the introduction of PVC-free blood bags, i.e. to supply an innovative blood bag for clinical testing and to verify stakeholder demand for the PVC-free blood bag. Activities aimed at the second objective will only start if the blood bags seem to become too expensive. Special activities to achieve the other objectives will be limited to ordinary dissemination measures.

PROJECT MANAGEMENT includes A (Action) 1: Project management; A4: Project meetings; A5: Monitoring the project's progress; A9: Audit; and A23: Final report
Jegrelius, with the support of a project management group, takes care of management, dissemination and contact with public bodies.

SUPPLY CHAIN COOPERATION FOR AN INNOVATIVE PVC-FREE BLOOD BAG
The objective is to construct an innovative PVC-free blood bag and evaluate its quality in vitro, as well as in a hospital environment. A specification of the properties for this bag has been developed by a Swedish purchasers group and is perfectly in line with EU specifications. It will be achieved in 6 steps:

A12: Production of compounds for films and tubes used in blood bags Compounds for films and tubes to be used in blood bags will be developed by the Danish SME MELITEK. MELITEK has more than 10 years' experience of developing, manufacturing and supplying non-PVC plastic compound resin (modified polypropylene compounds) used for primary pharmaceutical packaging applications.
A13: Production of film for the blood bags. These compounds will be the basis for the production of film for the blood bags. The Finnish WIPAK OY will be in charge here. WIPAK is one of the leading global suppliers of medical packaging, with long experience in the development and production of PVC-free films for the manufacture of soft containers for medical liquids.
A14: Production of tubes to be used in blood bags Production of tubes to be used in blood bags will be handled by Danish Totax, which has supplied products to global companies in the medical device industry and to clinics and hospitals for over 30 years.
A15: Production of a PVC-free blood bag Manufacturing a PVC-free blood bag will be done by Italian SME Haemotronics. SME has long experience of producing high quality plastic bags for medical purposes.
A16: Evaluation and monitoring of blood bags Performing in-vitro tests of the blood bags' quality will be the task of Karolinska University Hospital.
A17: User testing of blood bags Demonstration of the blood bags in a hospital environment will be done by RJ as well as calculations of the economic feasibility.

VERIFYING STAKEHOLDER DEMAND AND DISSEMINATION
The objective is to stimulate and verify the interest in replacing PVC blood bags with PVC-free blood bags. This includes actions that are basically the dissemination of the project's experiences. Some of them are ongoing. They are listed below according to start date.
A2: Website and media work Project homepages will be created at www.PVCfreebloodbag.eu and at the site of every partner. Press releases, reports, news and events will be presented in English and in the relevant national languages. Media information will be provided in at least four countries and at least three times in each country.
A3: Notice boards and dissemination of project information. Notice boards describe the project and are displayed at strategic places. Beneficiaries attend relevant conferences, presenting results as speakers, with posters or exhibition material.
A6 and 7: Organisation of first seminar A European seminar will strengthen awareness of the blood bag situation, increasing the group of potential buyers and users.
A8: Networking with other projects Initiation of networking with at least four other EU projects, in particular LIFE+ projects.
A10: Increase Demand Create awareness of why we need to phase out PVC blood bags. The target group is European healthcare organisations. A letter of intent and a petition will be used to show demand. A European purchasers group will be set-up. It will be a reference group to the project and it helps increase European and global demand.
A11: Production of brochures, reports, films, visitor maps etc.
A18 and 19: The Layman's Report will be used in the After-LIFE Communication Plan

A20: Technical publication based on Karolinska's evaluation results This will be based on the results of prototype laboratory testing and will be published in relevant journals.
A21 and 22: Four concluding European Workshops One workshop will be held in Sweden and the other three in strategic locations to achieve good dissemination.

Special measures to **reduce the carbon foot-print include**: i) Desk study of opportunities to decrease the carbon foot-print when substituting PVC for the innovative blood bags; ii) The project is being managed to minimise travel; iii) Events will be organised in a "green" climate friendly way, ie transportation, facilities, food and material; iv) Working with LIFE+ CLIRE - Climate friendly health and care so that products with a low carbon footprint will have a better chance of winning public tenders. LIFE09 ENV/SE/000347CLIRE).

Expected results (outputs and quantified achievements):
1. The project demonstrates that public healthcare and specialist companies in a multinational supply chain can cooperate to remove barriers to green solutions that are caused by the disinterest of major suppliers. Public bodies in Europe will have a successful example to copy when facing a private sector that does not want to deliver the necessary environmental improvements. This is particularly true for when the customer is very small in relation to an oligopolic supplier structure.
2. A prototype for an innovative PVC-free blood bag will be created and CE marked. It will be tested in-vitro, i.e. is it suitable for blood storage. Its practicality for hospital use will be demonstrated. It shall have been utilised for blood storage under controlled hospital conditions. It is expected that somebody in the market will be interested in buying the blood bag to undertake clinical testing. The customer could be a major blood bag supplier or a minor supplier of plastics products with the active support of those involved in the European purchasers group.
3. The project outcome shall convince plastics producers of the profitability of clinical testing.
4. There shall be documented interest in applying the new blood bags from at least 15 organisations in five EU member states.
5. Many people will be convinced of the need to replace PVC blood bags, as well as substituting PVC in the medical sector. The project's newsletter shall have a distribution of at least 200 subscribers. The project's websites shall exceed 50,000 visitors before the end of the project.
6. Five years after project ends. PVC-free blood bags will have reached a market share of 10% of the blood bags in Europe.

Can the project be considered to be a climate change adaptation project? Yes □
No □X

ENVIRONMENTAL PROBLEM

The specific and the general environmental problem

The proposal has been inspired **by the REACH regulation** and the EU Environment and Health Strategy. However, the activities of this proposal go further than those of the LIFE+ principal objective, Environment and Health. It targets the **LIFE+ priority 8. Chemicals and the priority area of action a) enhancing science-policy integration**….. Environment and Health is one of the four priority areas of the Sixth Environmental Action Programme. In line with this strategy, the proposal focuses both on integrated intervention and integrating stakeholders.

The environmental problem specifically addressed by this proposal is the lack of incentives among blood bag manufacturers to create PVC-free blood bags. This leads to a continuation of exposure to DEHP plasticiser and PVC plastics during blood transfusions, in spite of the EU's demand that something must be done about this violation of the precautionary principle.

This lack of incentives is an **example of a general problem**. In an oligopolic market structure, suppliers have limited incentives for environmental improvements. This is particularly so when the innovations would compete with their existing products and also would represent a marginal percentage of their future turnover.

Therefore, the demonstration focuses on a **methodology for public sector** bodies for procuring environmental improvements when ordinary suppliers have few incentives to offer them. Such improvements are badly needed to substitute harmful chemicals, including plastics such as PVC and polyurethane.

Defining and quantifying the specific environmental problem

The health sector is one of the largest sectors for public procurement in Europe. Research has shown that in 2001 there were already alternatives to the current PVC/DEHP blood bags that satisfied the needs for storage of red blood cells. However, the suppliers do not supply them.

Soft PVC is used worldwide in medical devices. To make the plastic soft and elastic up to 50% plasticizer is necessary. The most common plasticizer is the phthalate DEHP (di-(2-ethylhexyl) phthalate. **DEHP is classified as a reproductive toxin,** which means it may impair fertility and cause harm to unborn children. Patients and hospital staff are the exposed to leaching DEHP via fluids or lipids. **EU directive 2007/47/EC** regarding medical devices emphasizes the evaluation of the risks of using DEHP in devices for sensitive groups like newborns and pregnant women.

For precautionary reasons an alternative plasticizer is not a good solution. It does not solve the environmental problems of PVC itself. PVC may cause problems during production and at the disposal stage. Concerns regard the long-term environmental consequences of such substances at all stages of their lifecycles. These include **PVC use and emissions of high concern, bio-accumulation and persistent chemicals during production, high energy requirements, the use of heavy metal stabilizers and phthalates and the release of dioxins and greenhouse gases upon incineration.** Meanwhile, when **landfilled, PVC's toxic additives, such as cadmium, lead, organotins, and phthalates, can leach** from the plastic into landfill water (known as leachate), which can escape landfills and contaminate local ground water.

A PVC-free blood bag would have a big impact on long term health and the environment. There are currently no acceptable PVC/DEHP-free alternatives available for blood bags intended for red blood cells. Suitable materials for PVC-free blood bags exist, but such bags are not being developed. One reason why PVC/DEHP has been hard to replace is due to DEHP's stabilising effect on the red blood cells, giving a longer storage time. Another major reason is that the manufacturers and suppliers who could develop such blood bags are not motivated to do so. They need more incentives, like indications of demand from the purchasers.

In Europe some 16 million blood bags **affect some 10 million people** every year. This equals 2.7 million kg of plastics in the EU. Roughly 1.7 million kg are PVC while a million kg are phthalates. Replacing PVC bags in the EU with non-PVC will yield a reduction of approx 750 tons in waste due the lower density of polyolefins vs PVC.

The use of blood bags for red blood cells is the **most demanding health care application of PVC with DEHP plasticizer**. A successful demonstration for blood bags opens up for initially replacing it in all other blood related uses, and then all other uses in the health sector. Among these is its use in haemodialysis. While it is the only way to survive for dialysis patients, many patients know that with each cycle their bodies receive more of leaching poisonous plasticizing substances, often DEHP, from the PVC. This is why blood bags are the most important step in substitution of chemicals in the Health sector.

A specific problem is the exposure of **sensitive groups**. The biggest use for these groups is for haemodialysis. In the EU there are some 150,000 people that depend on very frequent dialysis. They need some 21 million tonnes of PVC and some 6 million tonnes of DEHP every year.

The need to address PVC issues was highlighted in the Green Paper on 'Environmental issues of PVC' at European community level COM (2000)469, on 26 July 2000. "The management of PVC waste should be assessed in the context of the European waste management policy"…. This is what the project aims to achieve, as it intends to create mechanisms to phase out the use of PVC in blood bags. At the same time, the intention is to get rid of harmful additives such as DEHP that are needed when using PVC. The proposal is also based on voluntary measures in line with the waste strategy.

As regards DEHP, the Commission has taken a clear stand. DEHP has been added to the CMR list (Carcinogen, Mutagen and Reproductive toxicant substances) in the EU. "On the basis of in vitro and in vivo toxicity studies, there are concerns for testicular toxicity, depressed fertility and reproductive developmental toxicity following oral exposure to PVC containing DEHP in children. This resulted in the banning of DEHP in soft toys in some areas" (European Commission, 1999). Furthermore the "EU directive 2007/47/EC on medical devices" emphasises the risks of DEHP in devices for sensitive groups.

Highlighting the general environmental problem

This demonstration sets an example for other public sectors in finding ways for environmental improvement when suppliers show little interest. The importance of public sector procurement differs between countries. **Public procurement is also regulated by European, as well as national, legislation.** Experiences of technology procurement are limited but inspiring. One way to describe the importance of this proposal is describing what LIFE+ priorities could be addressed in the future using similar methodology. The joining of forces to verify European customer demand for a technical solution is an easier way than legislation in achieving environmental objectives.

The specific environmental objective primarily addresses LIFE+ priorities, Chemicals and Waste and Natural Resources.

For **climate change,** the demonstration will strengthen public opportunities for being supplied with technical environmental innovations and it will also provide another example of how to use a market-based incentive to create environmental innovations.

The way to stimulate a necessary innovation is also relevant at least to LIFE+ objectives: **Water,** PPA a, **Air, Urban environment**, **Innovation, Strategic approaches,** PPA a.

National priorities for LIFE+

The issue that is specifically addressed by this proposal is included in the **National priorities for LIFE+**. The priority area under Chemicals, a) enhancing science policy integration....: For Sweden it relates to the environmental objective: "A non-toxic environment". This is a Swedish priority objective, since it has been estimated that it will not be reached by the year 2020. This specific problem also relates to the EU LIFE+ objective Waste and Natural Resources, priority area of action b) promoting waste prevention, which is a LIFE+ priority for Finland, Italy and Sweden.

The methodology that will be demonstrated is also of use for other LIFE+ priorities that have been included in the National priorities. **Climate change** is a national priority for Sweden, Finland and Italy. **Water** is a national priority for Sweden, Finland and Italy. **Air** is a national

priority for Sweden and Italy. **Urban environment** is a national priority for Sweden, Finland and Italy. **Innovation** and **Strategic approaches** are national priorities for Italy.

STATE OF THE ART AND INNOVATIVE ASPECTS OF THE PROJECT

The project is based on the findings of a previous project led by Jegrelius and on a combination of known technologies. The project name is: "Technology procurement of blood bags - a pilot case to stimulate eco-design". Blood bags exist in different polymeric material with additives and are used together with a storage solution. The demands on the bag depend on its use and for Red Blood Cell (RBC) bags there are very specific demands as regards the environmental, health and safety. The purchasers group consisted of county councils in Sweden. The objective was to stimulate the development of blood bags, which cause substantially less harm to health and the environment than existing blood bags do.

An outcome of the project is that it is very hard to motivate suppliers for environmental improvements when they stand to lose revenue from such improvements. This is particularly so in a global oligopoly situation, as is the case for the supply of PVC blood bags. That is why Jegrelius, using a partnership approach, has chosen to demonstrate in a LIFE+ proposal how such market problems may be circumvented.

Experiences of technology procurement for the environment from an unwilling market

EU policies have demanded the phasing out of PVC for more than ten years. Research has shown that opportunities exist. The valid question and the name of a publication is: "Can public procurement spur innovations in Health Care". It was published by the Swedish Research Authority, VINNOVA, in 2009. In 2007, Lena Stig from Jegrelius wrote a report for the Nordic Council of Ministers (NMC): Technology Procurement in Sweden. The Swedish Environmental Management Council (EMC), supported by Jegrelius Research Centre, published a report in 2008: "Technology Procurement – Tools for Promoting Innovations and New Environmental Technology". These experiences provide the expertise for the technology procurement aspect of this project.

The NMC report on Sweden states: "A large number of technology procurements have been performed in the energy sector during the 1990s, and within the local investment programme."

The EMC Report emphasises "... some aspects important to consider in case an eventual pilot technology procurement is carried out and which principally differ between the two areas of energy efficiency and substitution of health and environmentally hazardous substances. "...energy efficiency has had an economic benefit for the users as the main driving force. The phasing out/substitution of health and environmentally hazardous chemicals must rely upon other driving forces" The "economic benefits are considerably more difficult to directly link with the substitution of a certain chemical. The type of environmental problems that a group of buyers want to reduce/avoid through technology procurement can here instead even lead to increased costs. The "profit" a buyer can expect following technology procurement within the area of a non-toxic environment can most likely instead be linked to the positive health and environmental effects that can be achieved, however usually in a longer-term perspective."

The VINNOVA report states: "Examples of public procurements of innovations are, indeed, few in the world. Nevertheless, those that exist tell us an inspiring story. Our five original case studies from Europe and the US provide a clear message to policy makers. We conclude that the public sector has an important role as a partner to commercial interests in achieving the innovations in health care that otherwise would not materialise."

Two of the case studies refer to the UK. One case is about digital hearing aids in the UK, which now have superior qualities compared to earlier devices. The other concerns new designs for hospital furniture in the UK. The new furniture greatly reduces the risk of the spread of infection in hospitals.

The "overall recommendation is that policy makers should further explore ways to increase the use of public procurement of innovation in health care. The experience so far shows that this can result in better products, better quality of health services and ultimately higher growth and more employment."

Innovative aspects of technology procurement within this proposal

The project builds further on the experiences above. LIFE+ funding would provide a catalytic effect in this effort. It will make the following innovative aspects of technology procurement possible:

- to join a chain of suppliers based in several countries within the European Union

- to bypass the oligopoly of the traditional suppliers that have not acted to meet the demand in almost a decade.

- to use a combined technical and market approach for technology procurement for the health sector to create a situation in which there will be competition to provide the resources for clinical testing and marketing.

The results of the previous blood bags project include:

1. A market analysis "Technology procurement of blood bags", commissioned by Jegrelius Institute. It shows that there are no PVC-free blood bags and that the current blood bag producers have little incentives to make such bags available.

2. Properties specifications for the PVC-free blood bags

3. An effort to verify customer demand in Sweden

Technology procurement of blood bags: Market analysis

Blood bags are a complex product. Considerations when developing a new solution include functionality, environmental performance, quality, patient safety, handling, user friendliness and compatibility with other equipment. Manufacturers have stated that developing a replacement to today's DEHP-PVC bag is likely to take many years.

In order to stimulate the development of a substitute it is important to recognise the barriers which exist in order that the ultimate strategy can work towards overcoming those which block the stated objective.

There are four primary barriers which need to be addressed in order to promote the development of a substitute product:

(1) Political, Institutional and Legislative

(2) Financial

(3) Market Economics

(4) Technical

The main barrier today is a technical one. However, solving this requires manufacturers to be motivated through a clear and attractive customer demand or, alternatively, legislation. Different sized manufacturers will face different economic challenges, with the smallest lacking the resources to take the risk and the largest needing a clear incentive to change from the status quo.

The technical barrier can be specified:

• There is no technical solution which offers the performance of DEHP-PVC

• A new product requires a long lead time and testing to bring to market

• Low production capacity results in considerable unit costs

• Changes will be required in non-bag components (e.g. tubing) as well as in supporting infrastructure (e.g. storage systems)

The second major barrier is market economics:

• A DEHP-PVC replacement programme requires action by the whole supply chain

• The vested interests of traditional plastics producers and path dependency

• Low crude oil prices make non-fossil alternatives potentially less competitive

• Lack of clear demand

• Limited number of PVC-free vendors

Blood bags represent a niche product for PVC, with small volumes relative to other uses. The supply chain is dominated by a small number of specialised producers, generally wielding significant market power. These companies have integrated global operations and have invested significant sums in their current production capabilities, leading to path dependency. A non-harmonised regulatory environment makes any investment in a replacement bag more costly and difficult to justify for manufacturers. Overcoming these barriers requires legislation and/or concerted pressure from buyers at a level whereby the market size is clear and attractive. This means there is a need to demonstrate a clear European/global demand.

Research has shown that buyer-led initiatives have been successful in bringing forward PVC alternatives for nearly all other medical devices. Furthermore, the cost of these products is on a par with PVC versions in most cases. The lack of success in bringing forward an alternative for red blood cells seems to have most to do with the role of DEHP in stabilising red blood cells and the performance of PVC.

In light of the extended timeline for bringing a substitute product to market, undertaking a technology procurement is deemed unrealistic at this time. Discussions with suppliers of blood bags to the Swedish market and niche manufacturers of medical grade plastics have shown that there exists a willingness to explore a collaboration. The proposed project would leverage the combined skills of the manufacturers, the buyer group and Karolinska University Hospital. It is therefore recommended that further discussions are undertaken to see how a demonstration project could be established in the absence of a full procurement.

However, some years ago, the industry also showed a limited interest in supplying I V bags for similar reasons. When it was shown that it could be done, supply began and now a majority of IV bags are PVC-free. However, the demands on blood bags are much greater.

Market analysis has shown that major incentives are needed to create a PVC-free blood bag for testing. The approach of the project is twofold. The Life+ funds would be catalytic and a major contribution to meeting costs. However, a European purchasers group is also important to convince the industries of the business opportunities in this approach. Without such a pressure group there will be no development of blood bags that can be tested for regulatory purposes.

Specifications for the properties of PVC-free blood bags

This specification was drawn up by the purchasers group in the technology procurement ... project. The group included the leading Swedish experts on this issue. The objective is to stimulate the development of a non-PVC alternative to existing blood bags, including those for red blood cells.

The demand is for a blood container that will not be harmful to health and the environment, in accordance with the requirements specified. It will also fulfil the existing regulatory requirements for performance, quality and safety. One goal of the project is to find the best prerequisites for performing a real technology procurement of non-PVC blood storage and blood handling.

Products must meet the requirements defined in Swedish laws 2006:496 and 2006:497 and directives SOSFS 2009:28, and LVFS 2010:2. These national directives are based on EU directives 2005/62/EG, 2005/61/EG, 2004/33/EG and 2002/98/EG.

The specification includes the properties of the blood bags, as well as quality requirements regarding produced blood components. The material requirements have been specified for the blood containers/kit and for the packaging for blood containers/kit.

Verification of customer demand

The project has developed letters of intent and letters of commitment. These have been distributed for signature by a number of organisations in the healthcare sector, in Sweden as well as globally.

Innovative aspects that build on the previous project

The proposed LIFE+ project makes the innovations solicited by the previous blood bags project possible. The additional innovative aspects in relation to that project are:

1. A prototype blood bag will be produced and tested according to the specifications that have been drawn up.

2. Efforts fto verify customer demand will be considerably strengthened. It is much easier to verify demand for a product that exists and which only needs clinical testing to get to the market. The closing workshops will focus on presentation and discussions about how to introduce the innovation in member states. LIFE+ support would, considerably strengthen this, not just because of the resources involved but also because of the additional status it would bring to these efforts.

3. Based on the experiences of the project, the concluding workshops will also draw up recommendations for the phasing out of PVC from the health sector in leading European countries. It is hoped that every other EU country will be stimulated to create a strategy for phasing out PVC blood bags..

Technical conditions

The crucial technical issue is how to create blood bags that have the storage properties that are provided by the DEHP component in the PVC-free blood bags. However, a variety of observations on six weeks' blood storage without PVC/DEHP have been recorded. One of them is from the Hoxwort Blood Center in Connecticut, USA. A new solution for storage was combined with a polyolefin blood bag and the red blood cells could then be stored for six weeks. However, this blood bag is not on the market.

A supply chain is needed to turn known compounds into a blood bag for testing. This supply chain is basically integrated in the major companies that currently supply blood bags. The highly specialized expertise of four companies is needed to build such a supply chain outside of the big company suppliers. The preparations for this proposal have included the building of this supply chain.

Compounds for films and tubes to be used in blood bags will be developed by the Danish SME MELITEK. MELITEK has more than 10 years experience in developing, manufacturing and supplying non-PVC plastic compound resin, mainly based on modified polytehthylene and the polypropylene compounds used for primary pharmaceutical packaging applications.

The compounds will serve as the basis for production of film for the blood bags. WIPAK OY will be in charge of this. WIPAK is one of the leading global suppliers of medical packaging, with long experience in the development and production of non-PVC films for the manufacture of soft containers for medical liquids.

Tubes will be produced for the blood bags. This will be handled by Danish Totax. For more than 30 years, Totax has supplied products for companies within the medical device industry and directly to clinics and hospitals around the world.

Manufacturing a PVC-free blood bag will be done by Italian SME Haemotronics. This Italian SME has a long experience of producing high quality plastic bags for medical purpose.

Evaluation and monitoring of blood bags will include performing in-vitro tests of the quality of the blood bags. This will be the task of Karolinska University Hospital.

Demonstration of the blood bags in a hospital environment will be done by Jämtland County Council.

Innovative technical aspects

The innovative technical aspects include:

1. Production on an industrial scale will be introduced for another PVC-free plastic compound.

2. This compound will, for the first time, serve as the basis for production of a film. This film will have its first use in prototype blood bags.

3. The compound will also be used for production of tubes for blood bags for the first time.

4. Blood bags will be manufactured from this compound.

5. The compound will be tested in-vitro and for practicality of use in a hospital environment for the first time.

DEMONSTRATION CHARACTER

This is a demonstration project. The project will create PVC-free blood bags and test them. The purchasing power of the European health sector will be drawn upon to create the incentives needed to make industries deliver the prototypes for testing.

The project puts into practice, tests, evaluates and disseminates a new methodology for the healthcare sector. This innovative twofold approach is needed to remove barriers to the supply of PVC-free blood bags. It includes the creation of a prototype based on known technologies. However, these technologies have not been applied to the production of blood bags. It also includes the verification of the demand for such a blood bag. This method has been used by a Swedish group of blood bag purchasers; the project will extend it systematically to the European level and offer non-European organisations the opportunity to take part in verifying demand. This method has not previously been applied within the European healthcare sector. The LIFE+ funding has a catalytic effect in enabling the companies to work towards a goal that does not provide them with short-term profits.

This methodology is a new tool for bypassing suppliers who, in an oligopoly situation, do not want to deliver environmental solutions that the customers would like to buy.

The project has been designed to demonstrate whether the methodology works or not in the project.

The proposal is a logical next step in achieving a PVC-free blood bag. Previous steps are the outcome of a project managed by Jegrelius, aimed at making it possible for a Swedish purchasers group to use technology procurement to be able to buy PVC-free blood bags. Karolinska University hospital is a leading European hospital that was involved in the project. The output of the project includes:

1. Specifications for such a blood bag in line with EU standards.

2. A market study has established that there is very limited interest among current blood bag suppliers to provide a PVC-free blood bag.

3. Work to verify market demand, primarily in Europe, has been initiated by Jegrelius

4. An initiative by Jegrelius that identified a unique set of companies covering the supply chain for a PVC-free blood bag. They are committed to demonstrating that it is possible supply PVC-free blood bags. Demonstrating that the necessary steps have been taken to ensure that the foundations of these hypotheses have been appropriately secured (i.e. the type and amount of previous research needed).

The scale of the demonstration has been selected in order to allow the evaluation of the technical and economic viability of the proposed pilot on a larger scale. Major costs are involved in clinical testing of the blood bags before they can be put to actual hospital use. A company must assume responsibility for the clinical testing. The outcome of the market study indicates that if these two barriers are removed, there will be suppliers of PVC-free blood bags.

It could be argued that clinical testing should be included in the project. However, if that were the case, the project would become too long and too costly for a LIFE+ project.

Monitoring, evaluation and dissemination of the main project results and/or lessons learnt are an integral part of the project and its aftermath. This will be carried out in Actions:

Evaluation and monitoring of blood bags: Performing in-vitro tests of the quality of the blood bags will be the task of Karolinska University Hospital, and;

User test of blood bags: Demonstration of the blood bags in a hospital environment will be done by Jämtland County Council.

This demonstration project aims to encourage other stakeholders to use the techniques and methods demonstrated. In particular this goes for those facing other environmental problems

in not only in the health sector, but also in other sectors where public bodies face suppliers that are not keen on delivering the environmental improvements that are necessary.

EU ADDED VALUE OF THE PROJECT AND ITS ACTIONS

The specific environmental problem is the lack of incentives among blood bag manufacturers to create PVC-free blood bags. This is an **example of a general problem**. In an oligopolic market structure, suppliers have limited incentives for environmental improvements. This is particularly so when the innovations would compete with their existing products and would also represent a marginal percentage of their future turnover.

Therefore, the demonstration focuses on a **methodology for public sector** bodies to procure environmental improvements when the ordinary suppliers have little incentives to offer them. Such improvements are badly needed in the substitution of harmful chemicals, including plastics such as PVC and polyurethane.

The proposed project actions contribute to the achievement of European environmental objectives in a diversity of ways.

Benefits of solving the specific environmental problem

The project aims to deliver a prototype that has been tested and is ready for CE marking and a strong verification of the market demand for this product. Such a prototype is the necessary first step towards the creation of new blood bags. The objective is to remove the barriers that restrain current market actors from assuming responsibility for the necessary clinical testing. This will be either a big company or a small company with a strong support from blood bag purchasers.

As soon as good alternatives to PVC blood bags exist, there will be a political pressure to introduce them. However, there are significant national market barriers to the introduction of new medical devices. These will be addressed through presentations by leading national experts in the concluding round of workshops.

Of course, the major benefit is the value of a healthcare component that is less harmful to patients than PVC blood bags. We therefore expect that PVC-free blood bags will not cost more than the current PVC blood bags in a life-cycle perspective. Phasing-out PVC in blood bags also has the potential to marginally reduce costs regarding handling of waste. There is a 30% waste reduction due to the lower density of polyolefin based materials vs PVC.

The long-term effect is expected to be the total phasing out of PVC blood bags on a global level. The project creates an opportunity for this process. It will provide a functioning prototype and practical experiences of its use. Within a decade after the project's conclusion, it is expected to result in the near total abandonment of PVC blood bags, first in Europe and subsequently at a global level. The current Swedish figures for this use are expected to decrease by 50 tonnes of PVC and 30 tonnes of phthalates annually. The effects at European and global levels will develop proportionately. Phasing out is expected to have reached 95% 10 years after the end of the project.

The phasing out of PVCs and phthalates in blood bags will result in:

-Lower phthalate exposure for patients

-Less phthalates harming the environment

-An improved working environment in the health sector

-A considerable decrease in PVC waste from the health sector, which will significantly diminish dioxin waste

In Europe the phasing out of PVC blood bags with DEHP will remove exposure to these chemicals in blood transfusions for **around 10 million people** every year.

The use of blood bags for red blood cells is the **most demanding health care application of PVC with DEHP plasticizer**. A successful demonstration for blood bags opens up for first substituting all other blood-related uses, and then all other uses in the health sector. Among

these is use in haemodialysis. While it is the only way to survive for dialysis patients, many patients know that with each cycle their bodies receive more of leaching poisonous plasticizing substances, often DEHP, from the PVC. This is why blood bags are the most important step in substitution of chemicals in the Health sector.

A specific problem is the exposure of **sensitive groups**. The biggest use for these groups is for haemodialysis. In the EU there are some 150,000 people that depend on very frequent dialysis.

The substitution of PVC with DEHP will remove waste. The removal of PVC/DEHP from blood transfusions equals 2.7 million kg of plastics per year in the EU. Roughly 1.7 million kg is PVC while 1 million kg is phthalates.

In dialysis, around 21 million tonnes of PVC and 6 million tonnes of DEHP will be substituted annually.

Replacing PVC bags with non-PVC in the EU will yield an annual waste reduction of approx 750 tonnes due to the lower density of polyolefins vs PVC.

It is expected that the combined purchasing power of organisations involved in the project will make it possible to create the incentives needed for technical development. The new alternatives to PVC may also be tested in other sectors, in particular the food sector.

Benefits of demonstrating a way of solving the general environmental problem

The project will to serve as a role model for purchaser-driven Green Public Procurement in Europe. This is particularly the case for intra-sector purchaser co-operation and even more so for the health sector.

The project reflects the need for action in line with the Environmental Technology Action Plan. This goes in particular for underused environmental technologies that exist and for using targeted and effective incentives to the introduction of environmental technologies, as well as for reducing uncertainty about future market developments to boost investment in environmental technologies and for the need to build on the experience and the commitment of different stakeholders.

Creating a purchasers group within healthcare will provide a cost-effective way for individual health care units to take part and work in a long term perspective.

The project is a response to a major motivation for the REACH regulation: “73. Substitution of a substance …… posing an unacceptable risk.” Article 1 defines the aim and scope of the REACH regulation:

“1. The purpose of this Regulation is to ensure a high level of protection of human health and ……. while enhancing competitiveness and innovation.……

3. This Regulation …..for …….. and downstream users to ensure that they …….. use such substances that do not adversely affect human health or the environment. ….. the precautionary principle.”

Therefore it is expected to serve also as a basis for further development of EU-policies.

Transnational co-operation

The market analysis has shown that no current manufacturer of blood bags is willing to develop PVC-free blood bags. It has also identified suitable companies to do this in Italy, Denmark and Finland. This initiative stems from the Jegrelius Institute for Applied Green Chemistry in Sweden. Karolinska University Hospital is a leading hospital in Europe for the kind of testing that is needed. A blood bag cannot be achieved without transnational cooperation.

Other EU funding sources are not available

This cooperation does not fit with the Eco Innovation programme within the framework programme for Competitiveness and Innovation. Nor does it fit within the Framework Programme on Research and Development. The project attempts to put together existing technologies and test the result. It is expected to be too low a level of innovation for the Research Programme.

Geographical scope

The problems are of a global nature. It may well be that the organisation that assumes the responsibility for clinical testing is based outside Europe, but the solution is bound to be of major importance to Europeans. A number of Swedish organisations have already agreed to buy a PVC-free blood bag as soon as there is a supply available.

Transferability

This project is initiating a process to strengthen the phasing out of PVCs in blood bags. It addresses an old concern of the EU as well as that of health organizations in many countries. It also demonstrates a method for doing so. This method includes using the purchasing power of public organizations to create conditions that will lead to new technical and commercial solutions.

Cost effectiveness

There are those that assume that phasing out PVC is too costly and new PVC-free products often cost more initially. However, there are examples that show that when production volume goes up, price goes down. Examination gloves are one example were there has been a shift from phthalate to phthalate-free gloves. The difference is now nearly negligible and the difference in price between PVC and nitrile gloves is also reducing. Other PVC-free products, like IV bags, were price-competitive from the beginning.

EFFORTS TO REDUCE <u>THE PROJECT'S</u> "CARBON FOOTPRINT"

The efforts to minimise the carbon foot-print of the project will be continuously reviewed and updated throughout the project. This will be the subject of discussions within the Project Management Group as well as within the European purchasers group. Suggestions will be solicited from recipients of the project Newsletter as well as from visitors to the project home-page. Currently five activities are foreseen for the carbon footprint.

A desk study will be made to describe the opportunities to decrease the carbon foot-print when substituting PVC by the substance used for the innovative blood bags. The results will be specified for uses for blood bags, other blood-related applications, toher applications in the medical sector as well as for the food packaging sector. Geographically the EU-level, the European level and global level will be distinquished.

News of work to limit the carbon foot-print in the Health care sector will be disseminated through the project Newsletter.

The project is being managed to minimise travel. Management meetings will be held on-line in average every three months. The physical meetings of the management group will be limited to when meetings are anyway needed for the seminars/workshops. In order to maintain close cooperation, the project coordinator will visit each of the beneficiaries once during project implementation.

The seminars/ workshops will be organised as a “green” climate friendly seminar regarding transportation, facilities, food and material.

For the first seminar we will invite the LIFE+ CLIRE - Climate friendly health and care to deliver a presentation of its work. The project objectives include to improve the procurement system so that products with a low carbon footprint will have a better chance of winning public tenders. LIFE09 ENV/SE/000347CLIRE). This information will be followed-up. Participants to the First Seminar, Action 7 will be asked to provide information on the carbon foot-print of their attendance to the meeting.

The project will follow-up the effects this information has had on the behaviour of the participants. The first follow-up will be through a questionnaire six months after the seminar. The second follow-up is in-depth interviews during the concluding workshops, Action 22.

These interviewees are participants both to the first seminar and to one of the concluding workshops. The results of both follow-ups will be compared with the carbon foot-print of attendance to the First seminar.is being managed to minimise travel. Management meetings will be held on-line, on average every three months. In order to minimise the project's ecological footprint, special measures will be taken. Physical meetings of the management group will be limited to when meetings are needed for the seminars/workshops.

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TAKEHOLDERS INVOLVED AND MAIN TARGET AUDIENCE OF THE PROJECT (OTHER THAN PROJECT PARTICIPANTS)

The progress and results of the PVC-free blood bag project are of major interest to stakeholders on the local, regional, national, European and global levels. This particularly applies to public sector healthcare providers, as well to businesses, especially those involved in environmentally-friendly solutions in plastics as well as in chemicals, and it also includes the general public. Below is a description of how each kind of stakeholder will be involved in the project, as well as the methods for dissemination to that target group.

Healthcare, particularly the public sector

The main objective is to get these stakeholders to sign Letters of Commitment for buying PVC-free blood bags. A secondary objective is to stimulate the sector towards the phasing out of PVC.

The European health sector is to a large extent public. The use of the DEHP plasticizer is currently necessary in order to preserve red blood cells. However, the risk of a negative impact on human health is well-known. As soon as an alternative is available, it will be considered seriously. Even if the cost is twice as high as that for the current blood bags, it would only represent a marginal increase in the total costs for blood transfusion. In fact, the current blood bags only need PVC with the DEHP plasticizer for storing red blood cells. A set of blood bags for transfusion contains four blood bags and only one is for red blood cells.

This project has been initiated by major purchasing stakeholders in the Swedish healthcare sector, including Karolinska University Hospital. This is a leading actor at EU level and includes PVC issues among its fields of leading expertise. This ensures access to the appropriate networks for disseminating results within healthcare in Europe.

Health Care Without Harm, Vienna hospital association, Blood Alliance and European Red Cross will also be involved as subcontractors or as contributing expertise to the project's implementation. Representatives of these organisations have already expressed an interest in the project

The main target audience is purchasers of blood bags in the European health sector. It is also expected to involve regulatory bodies. The involvement of both these target groups is expected to hasten the entrance to the market of PVC-free blood bags. Karolinska has the right direct contacts to involve appropriate expertise in any EU country for the closing workshops on strategy for the dissemination of PVC-free blood bags within countries.

The methods for dissemination to this group are:

1. Finding interested people through networking with other projects
2. International initial project conference
3. Setting-up and use of a European stakeholder network and a European user group;
4. Distribution of project newsletter
5. Continuing and strengthening the work with letters of commitment to buying a PVC-free blood bag;
6. The project website.

Businesses in the plastics sector

The primary objective is to get a company to do clinical testing and

marketing for the PVC-free blood bag. The secondary objective is to get companies to develop other PVC-free blood applications in the medical sector. The third objective is to involve companies in using the new compound for further substitution of PVC-plastics in the food packaging sector

The main target audience are major companies that are able to take care of clinical testing and marketing of the PVC-free blood bag. A secondary target audience is other companies in the plastics sector.

Four companies that represent a supply chain involving various stages of the plastics expertise that are needed to create PVC-free blood bags will be involved in the project. They are an important part of the basis for dissemination to this target group. The method includes:

1. Information on the success of the two-pronged approach of the project through conferences, websites and newsletters
2. Direct marketing meetings between the companies that are beneficiaries of the project and their customers
3. Articles in professional journals aimed at the plastics sector.

Public sector outside of healthcare

In Europe and globally, the public sector is striving for environmental improvements. The objective is to stimulate other organisations to use a similar approach to remove barriers to environmental solutions.

The main target audience is politicians that have decision-making powers in the public sector in EU.

The methods include:

1. Offer presentations to European and national conferences, for instance on eco innovations or on healthcare sector development.
2. Networking with other projects to find suitable key persons to initiate such development.
4. Distribution of project newsletter
5. The project web site.

The general public

The objective is to provide information about the methods for promoting environmental innovation. The target audience includes people that are interested in environmental improvements. The methods include:

1. Media work
2. Distribution of project newsletter
3. The project website.

EXPECTED CONSTRAINTS AND RISKS RELATED TO THE PROJECT IMPLEMENTATION AND HOW THEY WILL BE DEALT WITH (CONTINGENCY PLANNING)

There are no major risks perceived in relation to project management and the budget. Should unforeseen difficulties occur, the beneficiaries will meet virtually, adjust and adapt the project. Monitoring of the project will ensure that the project coordinator and the project management group are observant of potential upcoming problems.

During as long a period as five years from the application date, **the biggest risk** is that one of the participating companies is bought by another company that is not interested in the project. The contractual agreement between the partners will certainly make sure that also new owners are obliged to fulfil their role in the project, but it is very difficult to force somebody to perform its tasks on time. Should such a situation occur, the beneficiaries will use their extensive knowledge of the plastic manufacturing sector to identify a possible replacement.

The blood bags will be delivered for in-vitro testing and testing by users at hospitals. **The second biggest risk** is that in spite of careful monitoring of the production process, the concluding tests will prove that the blood bags are not good enough. If so the project will fail on its specific technical objective. However, it is still likely to be able to prove that it is possible to establish a new chain of producers and verify stakeholder demand for a new and environmentally superior product.

The third biggest risk is that in spite of both having a prototype that works and verified demand from stakeholders, no major companies will be interested in undertaking clinical testing. If so, the beneficiaries, with the support of some of the organisations that have agreed to buy a new blood bag, will create a new partnership in order to obtain the clinical testing that is necessary before entering the general market.

The fourth risk is that the cost of the new blood bags will be considered too high for general application. The proposed cost for the blood bags will be discussed with the European purchasers group. If it is too high, the project will continue to work on fall-back alternatives. These include offering it primarily for sensitive groups like neonatal and chronically ill people, as well as considering an alternative based on using the new material only for the bag for red blood cells and using other PVC-free materials for the other bags.

The fifth level of risk is easiest to describe in relation to the steps of the production process.

MELITEK will produce the new compound industrially. The compound will be evaluated for suitable properties and reruns of this process have been foreseen in the time-schedule of the project.

Another crucial stage is the making of the film by WIPAK. There are a range of technical risks which will be met by corrective actions through granulate modification and a new run.

Totax will produce the tubings and evaluate their quality. If it is not satisfactory the process will be modified.

Haemotronics will produce the blood bags and evaluate their quality. If it is not satisfactory the process will be modified. Haemotronics, with input from the other partners, will also estimate a cost for PVC-free blood bags. This cost will be one important aspect in the feasibility of the proposed blood bag.

CONTINUATION AND VALORISATION OF THE PROJECT RESULTS AFTER THE END OF THE PROJECT

- Which actions will have to be carried out or continued after the end of the project?

The coordinating beneficiary, Jegrelius is a leading Swedish institute on technology procurements for environmental innovation, in particular for applied chemistry. It therefore has a major interest in maintaining its national reputation and expanding it to EU level with the help of the results of this project. The Jegrelius Institute is part of Region Jämtland and it will maintain a website and a newsletter to inform about the results of the project. It will also go to conferences and offer information.

The reputation of Karolinska University Hospital in combination with the results of in-vitro and in hospital testing will make sure that at least Swedish bodies for regulatory testing initiate the CE marking process. Since these blood bags have been an EU issue for more than 10 years other countries are expected to start regulatory testing as well.

All the beneficiaries will communicate project experiences at a diversity of national and European fora. The companies will also offer information to their customers and will market the products that they consider profitable.

- How will this be achieved, what resources will be necessary to carry out these actions?

Jegrelius and Karolinska are public bodies. Their staff are expected to offer such information as part of their jobs. The companies have an innovation to offer their customers. They will do so to the extent deemed feasible in each case.

The objective is to disseminate project experiences. These relate to:
i) the specific environmental problem addressed by this project. It is to remove the technological and the market barriers for introduction of PVC-free blood bags.
ii) the general environmental problem that the demonstration provides an example of how to solve by removing these barriers.

Methods employed:
A successful after-LIFE Communication depends on involving the stakeholders. These will be involved already during the implementation of the project.
The project coordinator will do a desk-study “Survey of opportunities for After-LIFE – communication. It will include inter alia:
i) a method to spread the experiences of technology procurement
ii) an approach to involve a suitable company in clinical testing. It will be a major supplier of medical devices or a small company in the sector with the support of blood bag purchasers.
iii) National strategies to introduce PVC-Free bloodbags
iv) Continuation of dissemination by the beneficiaries through ordinary business contacts, at conferences, the project web-site and through the project Newsletter.

The desk study will be discussed with the European purchasers group and at project meetings.

A draft after-LIFE Communication plan shall be presented at the concluding workshops. Suggestions will be solicited from the participants.
The after-LIFE Communication plan will be discussed and finally decided at meetings of the Project Management Group.

- To what extent will the results and lessons of the project be actively disseminated after the end of the project to those persons and/or organisations that could best make use of them (please identify these persons/organisations)?

National regulatory bodies for the healthcare sector are expected to start regulatory testing as soon as the prototype is available.

The results and lessons of the project will be actively disseminated after the end of the project to those persons and/or organisations that could best make use of them. These are the bodies in charge of regulatory testing for the healthcare sector in Europe.