LIFE + Environment Policy and Governance

TECHNICAL APPLICATION FORMS

Part C – detailed technical description of the proposed actions

Revised 30 May 2015

DETAILS OF PROPOSED ACTIONS

ACTION 1: Project management

Description :

Efficient and experienced project management is key to a project's success. Jämtland County Council has managed a wide range of projects, including EU funded projects. Personnel involved in those projects have been transferred to Region Jämtland. Its institute for applied chemistry is an organisation that is tasked with using applied green chemistry to speed up work on phasing out hazardous substances in products. It does this by motivating the entire chain, from demand to innovation and product development. This takes place through development projects, advisory services and cooperative partnerships.

Methods employed:

Project coordination by Jegrelius

There will be a full-time project manager, with administrative support that includes an economist from Region Jämtland throughout the whole period. A project communications officer will be employed part-time for this project, working with both administration and communication. They will closely monitor the project's progress and report to the Commission. Documentation, communication and dissemination of project information are the major tasks. The Layman's Report and technical project report are described in actions 19 and 23.

A multinational project requires special attention to its reporting procedures. Therefore, the Head of Economics from Region Jämtland participated in and met all partners at the main project-building meeting in late summer 2010. These procedures will be defined in the Partnership Agreement. In order to establish excellent working routines, the first report from the beneficiaries to the coordinating beneficiary will be delivered three months after the project's initiation. These reports will be carefully reviewed at the first physical project management group meeting, which will be co-organised with the first international seminar.

Activities within this action are recruiting subcontractors, making a detailed technical plan for the implementation phase, writing reports and arranging meetings. The project manager will visit all the other beneficiaries to learn more about the companies and their actions in the project. The administration system of Region Jämtland will be used. Actions 2, 3, 5 and 12 will be used for documentation and dissemination.

Subcontractor recruitment will take place according to European procurement legislation. Life+ templates for activity reports will be used. The Microsoft Project software will be used for detailed project plans.

Project management group (PMG)

The partnership agreement will detail the tasks of PMG. Its task will be i) to monitor project progress; ii) to agree to minor project revisions as proposed by the project coordinator; and iii) to decide on proposing considerable project revisions to the Commission.

The Head of Jegrelius Institute will also be the Head of the PMG. It will consist of one high-level representative from each of the beneficiaries, the project coordinator and the economist in charge of project reporting. In order to limit the carbon footprint, the PMG will only meet physically at the initial seminar and at the main closing workshop. The other meetings will be virtual, as described in Action 4, project meetings.

Constraints and assumptions:
Minor contracts are possible without procurement procedures. Major issues may occur at short notice. The partnership agreement will specify that any beneficiary can call an additional virtual meeting of the group within a fortnight.

Beneficiary responsible for implementation: 1

Expected results:
Project management will ensure the smooth running of the project and that necessary action is taken early if something goes wrong.

The output will include agreements with sub-contractors with skills from substitution and the biopolymer industry, graphic design, proofreading and translation. A part-time project communicator will be recruited as a temporary employee. Life + Requirements and project goals fulfilled. Satisfied Commission as well as satisfied project members.

Indicator of progress:

Appointment of project manager	01/09/2011
Appointment of Communications Officer	01/09/2011
First meeting of the project management group	01/10/2011
Initial Report	30/11/2011
A detailed plan for the implementation phase	01/12/2011
Inception Report	01/04/2012
Progress Report no 1	
Progress Report no 2	01/02/2013
Mid-term Report with payment request	30/09/2014
Progress Report no 3	31/12/2015
Final Report with payment request	01/03/2017

ACTION 2: Websites and media work
Description:
The internet sites www.PVCfreebloodbag.eu and www.jegrelius.se will be used for the communication and documentation of all project information. Press releases, reports, news and events will be presented in English. Links to all beneficiaries' websites will be used. www.MELITEK.com www.wipak.com www.totax.dk www.haemotronic.it Each of the beneficiaries will set up a project homepage in its national language within its website. Establishing the main project website will be done by the IT manager; this is estimated at 2 weeks initially and then less than 1 day per month for maintenance. Web design by sub-contractor and text and documents provided by project manager and project communicator.

Press releases will be issued on the project startup and on appropriate occasions such as seminars and milestones. Interviews with project members and articles will be offered to the media.
More intensive work at milestones, start of project and end of project. Media activities in countries other than Sweden shall be adapted by the beneficiaries in each country.
At least four articles will be offered to professional journals in English.

Methods employed:
Joombla software, graphic design by subcontractor, guidance exists in LIFE+ toolkit. Using available channels to send press releases. Associated beneficiaries will use open websites and extranets. Press releases and submitting articles to professional journals.

Constraints and assumptions:
All texts on the joint website will be available in English; some texts will be in Swedish, for example press releases intended for the Swedish public. Working documents will not be on the website, only completed documents. The number of activities depends partly on media interest and on the results of the project.

Beneficiary responsible for implementation:
1 will be responsible and monitor the activities that non-Swedish partners develop in their countries. Beneficiaries 3, 4, 5 and 6 will be in charge in their own country.

Expected results:
The project website will be continuously updated. It will receive at least 50,000 visits during the project's lifetime. The companies' websites will be created within 6 months of the project's initiation. They will be updated at least twice before the termination of the project.

There shall be at least three press releases in each of Sweden, Italy, Finland and Denmark, which will result in articles in newspapers. The total number of press releases is expected to exceed fifteen.
Articles in magazines and other professional media will be an important mode of dissemination. They will target the medical sector, in particular blood treatment, environmentalists, plastics manufacturers, if possible focussing on food packaging specialists and public procurement experts.

Indicator of progress:
Continuous information about activities. Media activities will be presented on the website.

Project Web site launched	01/10/2011
First Press-release in every country	01/11/2011

ACTION 3: Notice boards and the dissemination of project information
Description:
The project is disseminated through a number of actions. These include: 2: Websites and media work; this Action, Actions 6&7 First Seminar; 8. Networking with other projects; 10 Increase Demand; 11: Production of brochures, reports, posters, invitations etc. 8: After-LIFE Communication plan; 19: Final layman's report; 20: Technical publication based on the evaluation; 21 & 22 Final seminars.
The notice boards describe the project and are displayed at strategic places that are accessible to the public. Global customer demand will be important to convince the current major blood bag suppliers to work with the new blood bag. Each year Health Care Without Harm in US arrange a conference called CleanMed. It is probably the best single conference in the world to stimulate global demand for the PVC-free blood bag. One focus is on substitution of PVC in healthcare. The conference is well attended by proactive healthcare organisations and is an excellent channel for dissemination of project information and increasing the demand by for example petition. The project will apply for a poster presentation and speaker possibilities. There is also a possibility to buy an exhibition place.
The standard rate for the conference this year is 595dollars and 229 per night at the conference site hotel. More information is found at http://www.cleanmed.org/

Methods employed:
The project coordinator will attend relevant conferences, present the project and its results or gain support for PVC-free blood bags. Participation will be as speakers, with posters or with other exhibition material.
Notice boards include the link to the website

Constraints and assumptions: The LIFE logo will always appear on the notice boards. Dissemination activities will depend on the opportunities raised.

Beneficiary responsible for implementation: 1

Expected results:
At least 15 notice boards. Attendance at three conferences.

Indicator of progress:
Notice boards set-up 01/11/2011, 31/03/2013, 31/12/2013, 31/12/2014, 31/12/2014
Number of launched notice boards 4
Attended conferences with participation in exhibition or as a speaker. 4
Material ready to action 7 01/03/2012
Material ready to action 22 01/07/2016

ACTION 4: Project meetings for the Project Management Group
Description:
Online meetings every third month, with an average of two hours per meeting. The meetings will make it possible for each beneficiary to show results to the other parties on computer screens. Online meetings will be more efficient than video conferences in sharing results. Planning, status reports and discussions will be on the agenda.

Methods employed:
Online meetings will require new software/services only for beneficiary 1. A final decision on the techniques to be used will be taken on the basis of the available technology for such meetings in the second half of 2011.

Constraints and assumptions:
Technical problems are expected in the first online meeting. A telephone conference may be an alternative choice.

Beneficiary responsible for implementation: 1, but every beneficiary is expected to participate.

Expected results:
Good control of the project and continuous contact between the partners will be maintained through efficient, climate-saving meetings.

Indicator of progress:
Project notes
Short time and detailed action plan in the minutes from each meeting.
Verification that the detailed actions from previous meeting/meetings has succeeded.
Verification versus the timetable of the project that the time schedule is held.

ACTION 5: Monitoring the project's progress
Description:
The objective is to monitor and document the effectiveness of the project according to the action plan and budget. The project manager and personnel from the administration and economy units of Jämtland County Council will be in charge.

Methods employed:
A monitoring protocol will be used. Instructions about how to report will be written and sent to all associated beneficiaries. Personnel time will be reported on a monthly basis using the timesheet provided. The associated beneficiaries will report to the coordinating beneficiary according to the monitoring protocol every quarter and if major deviations from plan occur. The reports will be discussed in the project management group.

Constraints and assumptions:
If deviations from the plan occur, minor ones will be explained and major ones will be reported.

Beneficiary responsible for implementation: 1, but every beneficiary will report according to the monitoring protocol.

Expected results:
The project will work according to the project's plan and budget. Deviations will be identified at an early stage and subsequently acted on.

Indicator of progress:

Monitoring protocol	01/12/2011
Updating of monitoring protocol.	Every 3 months
Reporting by all beneficiaries	for each report

ACTION 6: Organisation of First seminar action 7
Description:
Full organisation of a European seminar from invitation to follow-up. It is suggested that the seminar take place in Copenhagen. Other more central cities in Europe can be considered.

Methods employed:
Booking of conference facilities, writing and distribution of invitations and programmes, booking lecturers, administration of registrations, cooperation with Health Care without Harm (HCWH). Local member organisations of HCWH can provide support.

Constraints and assumptions:
The site of the seminar will be chosen in order to be within easy reach for a majority of the prospective participants.

Beneficiary responsible for implementation: 2

Expected results: 150 people participating in the seminar
Indicator of progress: 50 registrations for the seminar

ACTION 7: First Seminar

Description:

The objective is to create a higher awareness of the blood bag situation and to increase the group of potential purchasers, buyers and users. The proposed title is “Opportunities for phasing out PVC from blood bags”. More specifically, a European blood bag purchasers group will be established and participants will be registered for the project newsletter.

Methods employed:

The seminar will be held within the first 6 months of the project in an easily accessible place in Europe, for example Copenhagen. It will be held lunch to lunch to increase networking possibilities.

The programme will include one presentation of the project and another one on how it relates to EU policy issues concerning the environment, public procurement, chemicals and waste. There will be special focus on a status report on the efforts to get organisations to sign letters of intent or the petition for PVC-free blood bags. It will be preceded by a presentation of the experiences of the Swedish purchasers group. Brief presentations from project partners will be included. Non-project speakers will include NGOs with an interest in the project’s topics and non-project blood bag purchasers. European specialists in public procurement of technology will be invited as speakers. These include the LIFE+ CLIRE - project (LIFE09 ENV/SE/000347CLIRE). Special care is taken to include interactive elements in the programme. Networking projects that are already identified and those that are not yet identified will be invited to offer poster exhibitions.

Constraints and assumptions:

Purchasers, buyers and users from European healthcare organisations will be the primary target group. After the seminar, a physical project meeting can be held without any extra cost or environmental burden for travelling.

Beneficiary responsible for implementation: 2, but every beneficiary will participate

Expected results:

The seminar will have 150 participants from a majority of EU countries. There will be representation from healthcare organisations, plastics manufacturers, public procurement experts and environmental NGOs.

A European blood bag purchasers group will be constituted. It will act as a reference group to the project, in particular concerning the increase demand Action and the After LIFE+ dissemination activities.

An additional dozen organisations will sign the petition for PVC-free blood bags within a month after the seminar.

The project newsletter will get another 50 subscribers. There will be 10 extra subscribers to news from the CLIRE project.

Indicator of progress:

Awareness and increased interest in the project. .
First seminar 01/03/2012
Percent of targeted number of participants %
Percent of targeted number of Newsletter recipients %

ACTION 8: Networking with other projects

Description:

Networking with other projects will be developed throughout the project. From the beginning this proposal shares some objectives and activities with four projects that will be approached for networking purposes:

1. MediSafe - Concept for the management of clinical waste based on environmentally sound policies, providing economic benefits and making medical waste safe, LIFE05 ENV/UK/000131
2. EPOW - European Pathway to Zero Waste: demonstrating the route to zero waste to landfill via end of waste protocols and building a recycling society, LIFE08 ENV/UK/000208
3. SUBSPORT - Substitution portal : moving towards safer alternatives, LIFE08 ENV/D/000027. "The goal of the project is to develop a web portal on safer alternatives to the use of hazardous chemicals. It will provide information on alternative substances and technologies, but also of tools and guidance for substance evaluation and substitution management. They also plan to:
   - Raise and measure awareness of substitution needs and the difficulties encountered;
   - Set up a network of at least 50 stakeholders, exchanging information and experience on substitution during and after the project duration; and
   - Organise workshops and expert forums."
4. CLIRE - Climate friendly health and care: Specific objectives of the project include:
   - To improve the procurement system so that products with a low carbon footprint will have a better chance of winning public tenders;
   - To establish a working methodology that can be employed by health clinics;
   - To increase the use of energy from renewable energy sources (LIFE09 ENV/SE/000347CLIRE)

Methods employed:

The project uses six modes for networking with other projects:

1. Exchange of knowledge.
2. Exchange of information about each other's projects through project newsletters and links on project websites.
3. Exchange lists of recipients for project newsletters.
4. Attend each other's events where appropriate.
5. CLIRE's experiences will be used for information to the participants at the first seminar, Action 7. 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 in both the first seminar and one of the concluding workshops. These follow-ups will be compared with the carbon footprint of their attendance at the first seminar.
6. Other cooperation as identified in direct contacts with these and other projects.

Constraints and assumptions:

We assume that the projects referred to above are interested in cooperation. This may be a problem for projects that have been terminated or which have no further activities after the first seminar for this project.

Beneficiary responsible for implementation: 1

Expected results:

Information, presentations or posters at each other's project events or websites.

Attendance to provide information at one event per project and reciprocal attendance at our first seminar.
A short and a long-term follow-up of the effectiveness of information about how to limit climate change according to the CLIRE project.

Indicator of progress:
Progress will be indicated by how many projects are involved in this cooperation and how many modes for cooperation are included with each partner.
Percent of listed number of project cooperations %
Number of modes for cooperation used for project

ACTION 9: Audit
Description:
An audit of the project's expenditure will be done by the supervising financial controller. It will be performed at the end of the project.

Methods employed:
There is an audit template report in the LIFE+ tool kit. The internal auditor for Jämtland County Council will be responsible for the audit certificate. The other beneficiaries send approved certificates to the auditor.

Constraints and assumptions:
We assume that every beneficiary will have an audit without problems.

Beneficiary responsible for implementation: 1

Expected results: Approved audit
Indicator of progress: Audit result 01/10/2016

ACTION 10: Increase demand
Description:
The objective is to remove one of the barriers for the introduction of PVC-free blood bags, i.e. to verify customer demand for the blood bags. The target groups are healthcare organisations and politicians that can influence decisions about healthcare. There will be synergy effects with actions 3 and 8 regarding conferences and events.

Methods employed:
The methods include purchaser group meetings, networking, work on a letter of intent and a petition for the removal of PVC blood bags. The beneficiaries will attend suitable fora to promote this verification of demand.

The crucial first step is to establish a European purchasers group. It will build on the experiences of the existing Swedish purchaser group. This first activity will be combined with the first seminar, action 7. Subsequently, work will focus on strengthening awareness of why we need to phase out current blood bags.

A letter of intent and a petition will be used to verify demand. The European purchasers group will act as a reference group to the project. It will be invited to support project activities and in particular the concluding workshops and the after LIFE+ dissemination plan. Development of material is included in this action.

Constraints and assumptions:
EU level is the number one priority, but global demand will help to motivate suppliers and facilitate the later implementation of new bags.

Beneficiary responsible for implementation: 1

Expected results:
During the project, 20 networking European organisations and 50 new organisations will sign the petition.

Indicator of progress:
The number of organisations that sign the petition
Total number of blood transfusions they do/year

ACTION 11: Production of brochures, reports, posters, invitations etc.
Description:
Preparation of material for actions 3, 4, 10, 7, 8, 19, 21, 22, 23

Methods employed:
Develop material, i.e. draft writing by project members, graphic design and proofreading or translation by subcontractors.

Constraints and assumptions: Layman's report and final technical report in action 19 and 23

Beneficiary responsible for implementation: 1

Expected results:
High quality production of 2 posters, 3 brochures, 4 invitations, 4 programmes and 2 reports

Indicator of progress:
Number of information products
Number of events at which information products are presented
Notice boards set-up 01/11/2011, 31/03/2013, 31/12/2013, 31/12/2014
Material ready to action 7 01/03/2012
Material ready to action 22 01/07/2016
Final report delivered 01/03/2017

ACTION 12: Production of compounds for films and tubes used in blood bags
Description:
Assessment of raw materials, planning and preparing trial and production-scale compound manufacturing, with purging of the production machine. The compound will be produced on a production-scale machine, requiring purging of the machine with sufficient run-up times to ensure continuous and trouble-free compound processing. Purging of blood bag material away from the compound extrusion machine is also necessary. The estimated time needed is 3 months after the reception of raw material. Five different prototypes are planned and this means 3-5 deliveries to beneficiaries 4 and 5.

Methods employed:
Reception, storage and testing of raw materials.
Purging of production machine with the raw material before compounding (waste).
Extrusion for reaching stable production process conditions (compound profile data)
Mechanical values to be tested in laboratory
Analyzing monitoring results for preparing technical data sheet
Final compound shall meet regulatory criteria set by an external test house (toxicological tests)
Costs will be estimated for production of compounds on an industrial scale.
In order to compare the new bag with existing PVC bags it is relevant to make a simplified life cycle assessment.

Environmental data will be collected to facilitate this simplified life cycle assessment. The lifecycle is divided in four steps were transport data is included in each step.
1) raw material, (type of material ex renewable, reused or waste)
2) production,
3) use
4) waste or reuse

Data about energy (type of energy, energy consumption ex kWh/kg), emissions (to air, water, land) and climate effects (ex CO_2 equivalents) will be collected.
This Action 12 focus on collection of data to step 1 and 2

Constraints and assumptions:
Raw material and production machine ensure a stable and high compound quality. Compounds usable for film and tubing manufacturing for blood bags.

Beneficiary responsible for implementation: 3

Expected results:
Non-PVC compounds which are suitable for the production of blood bags, as per the requirements in ISO 3826-1:2003, and the compounds being reproducible at defined production parameters.
An estimate of the price needed to pay for compounds that are produced on an industrial scale.
Environmental data about this step.

Indicators of progress:
Ready-made compounds that have suitable mechanical and barrier properties as per the requirements in ISO 3826-1:2003. They shall be extrudable into film and fabrication of blood bags. Further material shall have heat resistance to allow steam sterilization of bags without deformation.

A price estimate for the compounds	31/12/2013
Delivery of first compound to ben 4	20/11/2012
Collection of environmental data completed	01/07/2015

ACTION 13: Production of film for the blood bags
Description:
Assessment of the raw materials, planning and preparing the trial and production-scale film extrusion, with purging of the production machine. The film will be produced on a production-scale machine, requiring purging of the machine with sufficient run-up times to

ensure continuous and trouble-free film processing. Blood bag material must also be purged from the film extrusion machine. This is estimated to take 4 months. Work cannot begin before reception of the raw material. Five prototypes are planned. The running time for each prototype is 8 weeks and new runs are possible in five weeks.
The project is monitored continuously, and reported at given dates to keep it under control and according to the project requirements. Reporting of time will be on each individual therefore all are mentioned.

Beneficiary 4 is manufacturing the film.
There is a good understanding of the film granulates performance that are to be used.

Each film consists of at least 3 layers i.e 3 different granulates
For 1 run many films will be run to minimize the costs. Films will be tested tested to see if they meet the requirements of the final product

6 runs all together are needed to trim the films to meet the final product requirements.
Production line supervisor is in charge of the film production machine, and the personnel when the film is made. He will coordinate that the raw materials for the run will be at the Machine at the right time, and that the Machine running parameters are right. He is making the particle count measurements, and giving the line clearance to enable the production run. He will be filing in the reports for later review.
R&D Engineer is evaluating the film production and deciding how the film running is performed and continued during film production.

Methods employed:
Reception, storage and testing of raw materials
Purging of production machine with the raw material before the extrusion (waste)
Extrusion for reaching stable production process conditions (film profile data)
Mechanical values must be monitored.
Analyzing the monitoring results for preparing the technical data sheet
Final film to meet regulatory criteria via external testing house (toxicological tests)
The costs for production of films at an industrial scale will be estimated and an estimated price level will be indicated.
In order to compare the new bag with existing PVC bags it is relevant to make a simplified life cycle assessment.

Environmental data will be collected to facilitate this simplified life cycle assessment. The lifecycle is divided in four steps were transport data is included in each step.
1) raw material, (type of material ex renewable, reused or waste)
2) production,
3) use
4) waste or reuse

Data about energy (type of energy, energy consumption ex kWh/kg), emissions (to air, water, land) and climate effects (ex CO_2 equivalents) will be collected.
This Action 13 focus on collection of data to step 2

Constraints and assumptions:
The compound to be used, as well as a price estimate for it, will be an input from Action 12.
Raw materials and the production machine are expected to ensure a stable and high film quality.

Beneficiary responsible for implementation: 4

Expected results:
Non-PVC film which is suitable for the production of blood bags and the film being reproducible at defined production parameters
An estimate of the price necessary to pay for films that are produced on an industrial scale.
A set of environmental data about the production of film.

Indicators of progress:
Ready-made film that has suitable mechanical and barrier properties for blood bags (data sheets).

A price estimate for the films	31/12/2015
Delivery of first films to ben 6	01/04/2013
Collection of environmental data completed	01/12/2015

ACTION 14: Production of tubes to be used in blood bags
Description:
Assessment of the raw materials, planning and preparing the trial and production-scale tubing manufacturing, with purging of the production machine. The tubes will be produced on a production machine, requiring purging of the machine with sufficient run-up times to ensure continuous and trouble-free extrusion processing and sufficient quality for the tubes. Furthermore, ensuring capability for a constantly high level of quality. Estimated numbers of different tubes are 5 to 10.

Methods employed:
Reception and storage of raw materials
Purging of production machine with the raw material before the extrusion (waste)
Extrusion for reaching stable production process conditions and quality
Measurements and controlling dimensions to fulfil the technical data sheets
External testing of tubing to demonstrate that the tubing fulfils regulatory requirements
The costs for production of tubes at industrial scale will be estimated, as well as a price level.
In order to compare the new bag with existing PVC bags it is relevant to make a simplified life cycle assessment.

Environmental data will be collected to facilitate this simplified life cycle assessment. The lifecycle is divided in four steps were transport data is included in each step.
1) raw material, (type of material ex renewable, reused or waste)
2) production,
3) use
4) waste or reuse

Data about energy (type of energy, energy consumption ex kWh/kg), emissions (to air, water, land) and climate effects (ex CO_2 equivalents) will be collected.
This Action 14 focus on collection of data on step 2

Constraints and assumptions:
The compound to be used, as well as a price estimate for it, will be an input from Action 12.
Raw material and production machine ensure a stable high quality.

Beneficiary responsible for implementation: 5

Expected results:
Non-PVC tubing which is suitable for the production of blood bags and which is reproducible at defined production parameters becoming possible and which meets regulatory requirements.
An estimate of the price needed to pay for tubing that is produced at an industrial scale.
A set of environmental data from production of tubings

Indicators of progress:
Tubes that have suitable mechanical properties for blood bags.

A price estimate for the tubes	31/12/2015
Delivery of first tubes to ben 6	30/10/2014
Collection of environmental data completed	01/12/2015

ACTION 15: Production of a PVC-free blood bag
Description:
Pre-activities to define subassembly requirements and define quality control requirements. In this action, the technology best suited for welding, material combinations and general manufacturing parameters has to be defined. Several machine runs followed by tests and checks are needed to get the first working prototype. Moreover, some components that can not be sourced within the participants will be purchased (example: donor needle, blood filter). Several sets manufactured for internal evaluation followed by tests and checks are needed to get the first working prototype. The bags will be tested for fulfilment of CE marking acceptability, including technical and dimensional features. All tests will be performed for the final set and/or on significant sub-sets and selected tests for the earlier prototypes. The final set is a set of bags suitable for blood collection at donor site and blood processing, in action 16.
The bags will first be tested for fulfilment of internal specifications as subassemblies for the set manufacturing and then CE marking.
The production is performed in teams with a Supervisor and some operators following instructions. We consider to have 1 (one) supervisor that superintends to 2 operators working for bag making and assembly**.**

Methods employed:
Production and Quality Control. Biological test; cytotoxicity ISO 10993-5:2009, irritation ISO 10993-10:2010, sensibility ISO 10993-10:2010, acute system toxicity ISO 10993-11:2006, testing for impermeability to microorganisms and physical testing. (Testing for bag leakage, bubble test, visual test, dimensional testing)
Testing as per ISO 3826-1 and EU ph 8.0 01/2008:30203
Sterility cycle validation: ISO 11737-1 and ISO-11607

Costs for production of films at an industrial scale will be estimated.
In order to compare the new bag with existing PVC bags it is relevant to make a simplified life cycle assessment.

Environmental data will be collected to facilitate this simplified life cycle assessment. The lifecycle is divided in four steps were transport data is included in each step.
1) raw material, (type of material ex renewable, reused or waste)

2) production,
3) use
4) waste or reuse

Data about energy (type of energy, energy consumption ex kWh/kg), emissions (to air, water, land) and climate effects (ex CO_2 equivalents) will be collected.
This Action 15 focus on collection of data on step 2. Step 2, the production is divided in

1) Bill of materials with sourcing
2) Injection molding
3) Pre-assembly operations
4) Assembly operations
5) Sterile manufacturing of sets and definition of filling procedure for sterile filling with anticoagulant drug
6) Packaging evaluation and verification in laboratory conditions
7) Sterilization evaluation and verification in laboratory conditions
8) Sterile manufacturing of sets and definition of filling procedure for sterile filling with anticoagulant drug in industrial setting
9) Sterilization validation in industrial conditions

Constraints and assumptions:
It is assumed that good price estimates are received from the production of compounds, films, tubes and from the sterilization company.

Beneficiary responsible for implementation: 6

Expected results:
Blood bags that fulfil criteria for internal use as subassemblies for set manufacturing and CE marking.
An estimate of the price necessary to pay for blood bags that are produced at an industrial scale.
Environmental data about the production of PVC- free bags

Indicator of progress:
Test results
A price estimate for the sets 31/12/2015
Definition of best suited technology for welding, injection molding and pre-assembly operations
Definition of materials combination (film + tube)
Definition of bag design 31/06/2015
Define manufacturing general parameters
First bag delivered for evaluation 31/03/2014
Define sterile manufacturing and filling of prototypes 31/08/2015
Define sterilization main parameters of prototypes 31/08/2015
First set delivered for evaluation 31/08/2015
Define manufacturing general parameters of industrial sets 31/12/2015
Define sterile manufacturing and filling of industrial sets 31/12/2015
Define sterilization main parameters of industrial sets 31/12/2015
First industrial set delivered for evaluation 31/12/2015
Collection of environmental data completed 01/02/2016

ACTION 16: Evaluation and monitoring of blood bags
Description:
Blood sets prototypes are tested in the laboratory according to standardised methods. Measurements using routine methods will demonstrate the function of the prototypes as storage containers. The responsible lab will plan and manage the testing procedure. The responsible lab communicates with the other beneficiaries in order to coordinate the physical testing of the bags. Meetings and technical discussions with the manufacturers will take place if appropriate. This will take 2-3 months from start to end of each prototype. Two prototypes can be tested simultaneously.

Methods employed:
Standardised laboratory techniques and routine measurement methods for testing blood bags.

Constraints and assumptions:
No prototypes might fulfil the quality requirements for the purpose of blood storage and transfusion.

Beneficiary responsible for implementation: 2

Expected results:
One or two prototypes are recommended for further testing.

Indicator of progress:
Prototype is shown to be suitable for storing collected blood components and can continue to the process of CE marking in action 15
First Evaluation of a prototype performed 01/02/2015
Second Evaluation of a prototype performed 01/06/2015
Final evaluation of prototype performed 31/03/2016

ACTION 17: User test including economic feasibility study of PVC-free blood bags
Description:
The economical and physical performance and user friendliness of the blood bags will be demonstrated and evaluated by Jämtland County Council. Moreover, the objective is to get the users of the bags involved and suggest improvements.

Methods employed in a stepwise procedure:
1. On the basis of the price estimate provided by Haemotronics in Action 15, the project coordinator will assess the economic feasibility of the PVC-free blood bag. The estimated cost will be compared with the price of current blood bags. Moreover, it will be compared to the total cost of blood transfusions. This comparison will also include the relative cost for other blood-related uses of the material. If the European purchasers group considers it necessary, special studies will be made of the price in relation to the uses of special risk groups, such as neonatal.
2. Jämtland County Council will perform the physical user test itself. All Swedish county councils as well as members of the European purchasers group will be invited to join testing at their own expense. The two most suitable Swedish County councils will be selected, as well as every interested organisation represented in the European user group.
3. Simulation of blood handling will be used to imitate reality: Filling, centrifugation, separating, closing tubing, etc. The criteria for evaluation will be those presented in the requirements specification for the project called Technology Procurement of

Blood Bags. The evaluation will focus on the advantages and disadvantages in handling and usage of the bag.

4. The result will be included in the final project report, action 23, and presented at the concluding workshops.

Constraints and assumptions:
The net value of the decrease in climate pressure/blood bag is expected to be so low that it will be considered negligible from an economical point of view in the calculation of economic feasibility.

Beneficiary responsible for implementation: 1

Expected results:
A thorough evaluation of the blood bags' performance with a positive outcome

Indicator of progress:
The step-by-step progress as described above.
The presentation of the result to the European user group 22/10/2015, 01/04/2016
Presentations of the results at project meetings 31/09/2015, 31/12/2016, 01/04/2016
A non-PVC blood bag tested and approved according
to the Requirements Specification 31/03/2016

ACTION 18: After-LIFE Communication plan
Description:
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 market barriers to the 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 already be involved during the implementation of the project.
The project coordinator will do a desk study "Survey of opportunities for After-LIFE – communication. It will include:

i) a method to disseminate the experiences of technology procurement
ii) an approach to involving 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 for the introduction of PVC-free blood bags
iv) Continuation of dissemination by the beneficiaries through ordinary business contacts, at conferences, the project website and through the project's 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.

Constraints and assumptions:
After-LIFE actions are not in the project budget

Beneficiary responsible for implementation: 1

Expected results:
A plan shall be included in the final project report, action 23.
The plan shall be implemented because of the benefits it offers the involved stakeholders, including project beneficiaries.

Indicator of progress:
Desk study. Discussions at project meeting, review by European purchasers, draft after-LIFE communication plan, discussions at concluding workshops and final after-LIFE communication plan.

ACTION 19: Final layman's report
Description:
The writing and production of a layman's report, intended for the general public, describing the project, its objectives, actions and result. A 5-10 page long report that is easy to read and understand for the general public. The layman's report will be published in pdf format and printed in limited editions for the final seminars. The layman's report will be translated into Swedish, Danish, Finnish, Italian, German, French and Spanish.

Methods employed:
Writing in Word, proofreading, translation and graphic design. The European purchasers group will be used to ensure adaptation to the target group. For additional language presentations only the text will change between versions.

Constraints and assumptions:
Budget for printing belongs to action 11.
Additional language versions will not be printed, but only available on the Internet.

Beneficiary responsible for implementation: 1

Expected results:
A short and easily accessible report in both paper and electronic format at the end of the project.

Indicator of progress:
Distribution of Laymans' report 01/03/2017

ACTION 20: Technical publication based on the evaluation results of blood bags
Description:
A technical report is written based on the results of the laboratory testing of the prototypes.

Methods employed:
Ordinary routines for writing a technical report.

Constraints and assumptions:
The time from delivery of an article to a scientific journal until acceptance and publication cannot be influenced by the members of this project.

Beneficiary responsible for implementation: 2

Expected results:
Publication in a scientific journal.

Indicator of progress:
Report accepted by a relevant journal 01/01/2017

ACTION 21: Organisation of Concluding Workshops action 22
Description:
The task is the full organisation of four European concluding workshops, from invitation to follow-up. Four workshops are needed in order to limit the number of participants to allow an interactive exchange about how to introduce PVC-free blood bags in European countries. Target groups are blood bag suppliers and healthcare organisations, as well as environmentalists and the people involved in public procurement.

One of the workshops will be held in Sweden and the other three in strategic places in Europe in order to achieve good dissemination, while limiting the average travelling distance and thus the carbon footprint. The workshops will be one-day meetings incl. an evening social activity. Every beneficiary will be involved in the concluding workshops.

Four key persons in four selected European countries will be asked to come to each workshop. They will be asked to present a strategy for how to facilitate the introduction of PVC-free blood bags in their country.

These workshops will be organised as “green”, climate-friendly events regarding transportation, facilities, food and materials. Exhibitors regarding other examples of phasing out PVC in health care will be invited, as well as other parties that are interested in this demonstration of a public procurement effort.

Methods employed:
Booking of conference facilities, writing and distribution of invitations and programmes, booking 4 external lecturers for each seminar, administration of registrations. Production of material, action 11.

Constraints and assumptions:
If the resulting blood bag does not reach the proposed quality, we will have to decrease the number of workshops.
The budget assumes real life meetings. However, when the workshops take place in early 2015, the development of the blood bags, as well as technical and logistical conditions, may be such that the outcome of the meetings will be almost as good if they are held virtually. This matter will be reviewed by the project management group as well as by the European purchasers group.
We assume that key persons in key countries are willing to develop and present a strategy for the introduction of PVC-free blood bags in their country.

Beneficiary responsible for implementation: 1

Expected results:
50 people registered for each workshop

Indicator of progress:
Initiation of organisation for final workshop 01/03/2015
Number of registrations to workshops

ACTION 22: Concluding Workshops
Description:
The objectives of the concluding workshops are to disseminate the project's methodology and to enhance the market introduction of a PVC-free blood bag. The strength of the outcome of these workshops shall provide enough commitment and incentives to convince suitable stakeholders to engage in clinical testing of the PVC-free blood bag. The design of the workshops is presented in Action 21.

Methods employed:
Interactive information and communication with professionals. The discussions will focus on lessons to be learned. These have two foci. The first is which lessons can be learned from the cooperative effort between public bodies and private companies in removing two barriers to the introduction of PVC-free blood bags. The second is which lessons can be learned from the strategies presented on the introduction of PVC-free blood bags in a particular country.
Other possible content to be discussed: time schedule for introduction of the product on the European marker, ways to speed up possible barriers in the legislation, facilitation of CE marking ….
The project partners will interview participants in the first seminar about their experiences in relation to the information of the CLIRE project on work on climate change in the health sector.
The project will present at least one report summarising the workshops for each focus. The design and distribution of these reports will be discussed at meetings with the European user group as well as with the project management group.
Representatives of public authorities that will be invited to facilitate the consideration of the project results in future legislation are on EU level connected to the Health and Consumers Directorate. On national level suggested authorities are given by examples related to the Swedish structure for organizing issues related to human health: Representatives from national ministries for health care issues plus Medical products agency, National Board of Health and Welfare and similar authorities.

Constraints and assumptions:
The same constraints as indicated for Action 21.

Beneficiary responsible for implementation: 1

Expected results:
Four European international workshops attended by selected healthcare providers and European countries, as well as interested parties among plastics manufacturers and in public procurement.
Reports on lessons learned from these workshops.
50 new organisations shall sign the petition for PVC-free blood bags.
There will be an input to the follow-up of the CLIRE information at the first seminar.

Indicator of progress:
Number of attending people, as well as number of countries they represent.
Number of additional petitions for PVC-free blood bags that are signed by the organisations of the workshop participants between the invitation to the workshop and the end of the project. Reports are available from the workshops.
Final Workshops 01/10/2016

ACTION 23: Final project report
Description:
Final project report of maximum 56 pages in English

Methods employed:
Templates are available. The report will be written by the project coordinator with the professional input of every beneficiary. It will be reviewed by the European purchasers group.

Constraints and assumptions:
The report shall be submitted no later than three months before the end of the project.

Beneficiary responsible for implementation: 1

Expected results:
Approved report both in pdf and in print

Indicator of progress:
Final project report 01/03/2017

DELIVERABLE PRODUCTS OF THE PROJECT

Name of the Deliverable	Code of the associated action	Deadline
Project Web site launched	2	01/10/2011
Notice boards	3	01/11/2011
A plan for the implementation phase	1	01/12/2011
Monitoring protocol	5	01/12/2011
LCA of PVC blood bag – additional deliverable	3	23/03/2012
Presentation of LCA	7	08/02/2012
Activity reports according to table below-Milestones	1	
Audit result	9	01/10/2016
Final Layman's Report	19	01/03/2017
Technical report	20	01/01/2017
Publication of the technical report	20	01/01/2017
LCA of the new PVC-free blood bag	22, 11	01/03/2017
After-LIFE Communication Plan (included in final report)	18	01/02/2017
Final project report	23	01/03/2017

MILESTONES OF THE PROJECT

Name of the Milestone	Code of the associated action	Deadline
Project start	1	01/09/2011
First seminar	7	01/03/2012
Production of the first PVC-free prototype	12-15	01/07/2012
First Evaluation of a prototype performed	16	31/12/2015
A non-PVC blood bag tested and approved according to the Requirements Specification	15,16,17	30/03/2016
Final Workshops	22	01/11/2016

ACTIVITY REPORTS FORESEEN

Please indicate the deadlines for the following reports:

- Inception Report (to be delivered within 9 months after the project start);
- Progress Reports n°1, n°2 etc. (if any; to ensure that the delay between consecutive reports does not exceed 18 months);
- Mid-term Report with payment request (only for project longer than 24 months)
- Final Report with payment request (to be delivered within 3 months after the end of the project)

Type of report	Deadline
Initial Report – included in inception report	30/11/2011
Inception Report	01/04 /2012
Progress Report – not required by EC	01/08/2012
Progress Report no 1	01/02/2013
Mid-term Report with payment request	30/09/2014
Progress Report no 2	28/02/2016
Final Report with payment request	01/03/2017

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TIMETABLE

List all actions ordered by number and using their numbers or names. Tick as appropriate. (Remember that projects cannot start prior to the date of the signature of the grant agreement)

Action	**2011**		**2012**				**2013**				**2014**				**2015**				**2016**				**2017**
Number / name	III	V	I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV	I
1 Proj Man	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
2 Web& media		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
3 Dissem. Not board		x					x			x				x			x			x			
4 Project meetings	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
5 Monitor		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
6 Org sem		x																					
7 First sem			x																				
8 Network				x			x					x	x							x			
9 Audit																	x				x		
10 Demand			x				x				x		x				x			x			
11 Info prod		x												x		x			x			x	x
12 Compound		x	x		x	x	x	x	x	x	x												
13 Film			x		x	x	x	x	x	x	x				x	x	x	x	x				
14 Tubing			x		x	x	x	x					x	x	x	x	x						
15 Bag				x	x	x	x	x	x	x	x	x	x	x	x	x	x						
16 Evaluation					x				x			x			x	x	x	x	x	x			
17 User tests														x	x	x	x	x	x	x			
18 After-LIFE																		x	x	x	x		
19 Layman's																		x	x	x	x	x	x
20 Tech pub																			x	x	x	x	x
21 Org sem														x	x	x	x	x	x				
22 Final sem																				x	x	x	
23 Final report																			x	x	x	x	x