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Critical review of the study "Life Cycle Assessment, LCA, study of PVC blood bag"

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Executive summary

This report presents the findings of a critical review of the study “Life Cycle Assessment, LCA, study of PVC blood bag”. The LCA study was carried out by eco2win AB within the project “LIFE+ PVCfreeBloodBag”. The critical review has been commissioned by the European Council of Vinyl Manufacturers (ECVM) and carried out by Professor Adisa Azapagic at the University of Manchester.

Overall, this critical review has found that the LCA study is inadequate because it fails to follow the following criteria normally expected from LCA studies:

- the methods used to carry out the LCA are not consistent with the LCA ISO standards 14040/44;
- some of the methods used are not scientifically and technically valid;
- the assumptions are unclear, inconsistent and in some case unjustifiable, misleading and biased;
- the interpretation of the results is biased against PVC and does not reflect in full the findings and limitations of the study; and
- the study report is not transparent with respect to the assumptions, data, calculation methods and results.

The above findings are based on the following the specific findings of the critical review:

- The goal of the study as defined is inappropriate as it suggests that the study is biased against PVC.
- Only three environmental impacts have been considered – climate change, health impacts and natural resources - so that the study does not represent a full LCA study.
- The reasons for considering these three environmental impacts are neither clear nor justified.
- The data are inconsistent and in some cases too old.
- The inventory results appear in places to be either inconsistent or wrong.
- Only a limited number of greenhouse gases have been considered which could mean that the climate change impacts for both types of blood bag are underestimated.
- The old characterisation factor for methane (21 kg CO_2 eq./kg CH_4) has been used which means that the results for the climate change impact are further underestimated.
- The choice of the impact assessment methods does not represent the state-of-the-art in LCA.
- It is difficult to interpret the results for the health impacts and check their validity as the assumptions are unclear or unjustified and the results have not been explained or put into perspective.
- The study puts a lot of emphasis on the health impacts without considering or discussing the large uncertainties associated with these estimates, particularly as the methodology for estimating health impacts is still in development.
- In particular, the results for the PVC “uncontrolled waste incineration” scenario should be interpreted with care as it is not clear what assumptions have been made with respect to dioxin emissions.
- Similarly, the results related to the impacts from DEHP should be interpreted with caution as they do not take into account ambient exposure.
- The assumptions on the leakage and uptake of DEHP appear to be arbitrary as they are not supported by evidence or published references.
- The interpretation of the health and other impacts appears to be biased against PVC and may be misleading for the reader.

In conclusion, the goal of this LCA study appears to be motivated by a desire to phase out PVC blood bags regardless of the actual LCA results (see section 1.1., pg 10 of the report):

> *“The purpose of this life cycle assessment is to serve as information for the development and establishment of demand and production of PVC free blood bags.”*

Therefore, the results of the study should be interpreted with this in mind.

1. Background

This report presents the findings of a critical review of the study "Life Cycle Assessment, LCA, study of PVC blood bag". The LCA study was commissioned by Jegrelius Institute for Applied Green Chemistry, Regional Council of Jämtland, and was carried out by eco2win AB within the project "LIFE+ PVCfreeBloodBag" (Carlson, 2012).

The critical review of the LCA study has been commissioned by the European Council of Vinyl Manufacturers (ECVM) and carried out by Professor Adisa Azapagic at the University of Manchester. The reviewer is independent of both the authors of the LCA study and the ECVM.

The critical review is based entirely on the LCA study report that was available in the public domain and there were no interactions or discussions of the reviewer with either of the authors of the study or ECVM during the peer-review process. At the time of writing of this critical-review statement, the report was available on the following web site: http://www.pvcfreebloodbag.eu/.

In assessing the LCA study, the critical review followed the main guiding principles for carrying out LCA studies defined in the ISO 14040/44 standards (ISO, 2006a&b) with the aim of finding out if:

- the methods used to carry out the LCA are consistent with these ISO standards;
- the methods used are scientifically and technically valid;
- the assumptions and data used are appropriate and reasonable;
- the interpretation of the results is valid and reflects the findings and limitations of the study; and
- the study is transparent, consistent and impartial.

The findings of the critical review are summarised below, following the phases of the LCA methodology: goal and scope of the study, inventory, impact assessment and interpretation.

2. Critical-review findings

2.1 **Goal of the study** (sections 1&2 of the study report)

The goal of the study is defined in section 1.1, stating that:

> *"The purpose of this life cycle assessment is to serve as information for the development and establishment of demand and production of PVC free blood bags".*

This suggests that the study is motivated by a desire to phase out PVC blood bags even before the environmental impacts have been identified and quantified. Thus, the goal of the study as defined is inappropriate as it indicates that the study is biased against PVC.

Furthermore, at this stage it is not stated that the comparison will be made with (hypothetical) HDPE bags, so that this remains unclear until section 1.3, where this is mentioned only in passing. The intention to compare the two types of bag should have been made clear in the definition of the goal of the study.

In section 1.3, it is also asserted that:

> *"To make the quantitative result meaningful and easy to understand, two reference points are established: One is the relationship between the potential*

human health impact caused by the transfusion of DEHP - contaminated blood and the human health impact caused by chlorinated substances throughout the life cycle."

It is not clear why the quantitative results would be *"meaningful and easy to understand"* if these two impacts are considered. Instead, the reason(s) for using these two impacts should have been stated and justified fully.

It is stated that (pg. 15):

> *"This* [energy recovery] *is not included here, since it would not add to the clarity of the study."*

"Clarity of the study" is an important but not a sufficient reason for excluding energy recovery from incineration, particularly as most incinerators in Europe recover energy. Therefore, this assumption is not justifiable (albeit made for both types of blood bag).

It is also unclear where the description of the PVC blood bag manufacturing process comes from as no references are quoted (pg. 14/15). The same applies for the HDPE bags, particularly as these currently do not exist.

Conclusions for the Goal of the Study:

- **The goal of the study as defined is inappropriate as it suggests that the study is biased against PVC.**
- **The intention to compare PVC with HDPE blood bags is not declared in the goal of the study.**
- **It is not made clear or justified why only three environmental impacts are considered in the study.**

2.2. Inventory (section 3 of the study report)

Data sources

The geographical location/region considered in the study is not specified but Plastics Europe data were used for both PVC and HDPE. Therefore, it is inferred from this that Europe is the location assumed in the study. Plastics Europe data are most widely used for LCA studies of plastics, so that this is an appropriate source of data for this study.

However, if Europe is the region assumed in the study, then it is unclear why the data for electricity for the OECD countries rather than Europe have been used. This introduces data inconsistency. The data for electricity are also too old representing the mix in 1997/98 (see page 40). Instead, a more recent electricity mix for Europe should have been used.

The use of recognised databases such as Ecoinvent (2010) or PE International (2010) would have increased the reliability and credibility of the study.

Conclusion for Data Sources:

- **The data are inconsistent and in some cases too old. The use of the state-of-the-art databases such as Ecoinvent and/or PE International would have increased the reliability and credibility of the study.**

Modelling, calculations and assumptions

An in-house excel file seems to have been used rather than a recognised LCA software package. While this is acceptable, it is not clear where the background data came from (except for the electricity) and how it was possible to model all the background systems.

It is assumed that oil is used in incineration to increase the flame temperature and control the emissions of dioxins. However, the justification for this assumption is not appropriate and appears to be biased against PVC (section 3.2.2 A. pg. 19):

> *"It is not an entirely realistic assumption, but makes it easy to understand that the oxidation of PVC and the emission cleaning is made on the expense of such an amount of energy resources."*

Furthermore, the assumption that no addition of oil to the incinerator in the 'uncontrolled waste PVC incineration' scenario leads to *"much higher dioxin emissions"* (section 3.2.2 B. pg. 19) is non-specific and no published reference is offered in support of this assertion. In any case, as the Waste Incineration Directive (now superseded by the Directive on Industrial Emissions) regulates dioxins from waste incineration in Europe, the emissions must be below the prescribed limits.

It is also not clear what is meant by the *"additional energy"* used for incineration of HDPE bags (3.2.2 C. pg. 19):

> *"The controlled waste incineration of HDPE means that it burns with the same additional energy as the controlled waste, leading to perfect oxidation and only carbon dioxide emissions."*

It is not clear what assumptions have been made for the emissions of dioxins from PVC incineration.

Conclusion for Modelling, Calculations and Assumptions:

- **The assumptions are unclear, inconsistent and in some case unjustifiable, misleading and biased.**

Inventory results

The results in figures 5 and 6 appear inconsistent or wrong. Both figures represent the total CO_2 emissions for the three alternatives (PVC 'controlled' and 'uncontrolled' and HDPE) but show quite different results: figure 5 shows the totals to be between 0.35-055 kg CO_2 per bag and figure 6 around 2 kg CO_2 per bag. It is not clear which result is correct.

Figure 6 also indicates that the only GHG in the life cycle of both bags is CO_2. This cannot be true so that these results appear to be wrong.

It is not clear what assumptions have been made in Figure 9 on the emissions of dioxins from 'uncontrolled' incineration.

It is stated in Figure 11 that:

> *"It was expected that the emissions of chlorinated substances are higher for PVC/DEHP, and the presented tables show this clearly".*

This is stating the obvious as HDPE does not contain chlorinated substances. This is typical of the rest of the report which suggests a bias as it attempts to 'emphasise' the 'negative' aspects of PVC bags. Similar statements are not found for HDPE. Further evidence of this is found in the Impact assessment section (see below).

Conclusion for Inventory Results:

- **The inventory results appear to be either inconsistent or wrong. The interpretation of the results appears to be biased against PVC.**

2.3. Impact assessment (section 4 of the study report)

The use of Ecoindicator 99 as one of the impact assessment methods is appropriate. However, the choice of the other methods is unusual as both the EPS and EDIP methods are now quite dated and rarely used. On the other hand, CML 2 (Guinée, 2001), one of the most widely-used impact assessment methods, has not been used. The ReCiPe method (Goedkoop et al., 2008), which combines the CML and Ecoindicator methods has also not been considered.

Furthermore, only a limited number of impacts has been considered in the study: human toxicity, natural resources and climate change. Therefore, this study does not constitute a full LCA.

It is asserted (pg 16) that including the other impacts

> *"would have contributed to neither the clarity nor the result of the study."*

This is not a valid justification for excluding other impacts. An LCA study should consider all the impacts relevant to the systems being studied which in this case would include acidification, eutrophication, ozone layer depletion and different eco-toxicity impacts.

Conclusions for Impact Assessment:

- **Only a limited number of impacts have been considered so that the study does not represent a full LCA study.**
- **The choice of the impact assessment methods does not represent the state-of-the-art in LCA.**

Climate change

Only four GHG have apparently been considered - CO_2, CH_4, N_2O and HCFC - which means that for both systems the impacts on climate change may have been underestimated.

The old characterisation factor for CH_4 has been used (21 instead of 25 kg CO_2 eq./kg CH_4; see Annex C of the LCA study) despite the assertion that the latest IPCC factors have been used (see page 16 of the study).

It is implied that PVC bags have "severe human health risks" (section 4.2.2, last paragraph on pg 26):

> *"....to substantially reduce severe human health risks as in this case."*

This is a further example of an exaggeration and bias against PVC – if such risks were so severe, PVC as a material would have been banned long time ago.

On the other hand, for instances where HDPE bags have higher impacts than PVC, as calculated in the study, this is not necessarily mentioned or discussed. For example, Figure 14 shows clearly that HDPE is a worse alternative than PVC for climate change. However, this is not stated in this section. The same is true for the natural resource use in Figure 20, whereby the HDPE bag is much worse than the PVC for two of the three impact methods considered – however, this is not mentioned or commented on in that section.

Conclusions for Climate Change:

- **Only a limited number of GHG has been considered which could mean that the climate change impacts for both systems are underestimated.**
- **The old characterisation factor for methane (21 kg CO_2 eq./kg CH_4) has been used which means that the results for the climate change impact for both bags are further underestimated.**
- **The interpretation of the results indicates a bias against PVC.**

Human health (HH)

Three different methods are used to assess HH: Ecoindicator 99, EDIP and USEtox. Of these, Ecoindicator is the most appropriate as EDIP is dated and USEtox does not allow consideration of all substances in the life cycle of the two system and thus has limited value for use in LCA. However, as commented previously, other methods for estimating the health impacts could have been used, including CML 2 (Guinée et al., 2001) and ReCiPe (Goedkoop et al., 2008).

The main difference in the results is found between the PVC bags for the "uncontrolled waste incineration" scenario and the HDPE bags. Since the assumptions on the "uncontrolled" emissions have not been revealed in the report it is difficult to interpret these results. Furthermore, as incinerators in Europe are subject to Waste Incineration Directive, it is only valid to consider these results if the emissions are within the limits prescribed by the Directive.

It is not possible to relate the data in table D7 in Appendix D to the results shown in Figures 15 and 16 for human health impacts so that it is not clear how the results in these figures have been arrived at. This does not help towards the transparency of the study.

The HH impacts in Figure 18 are mainly related to the production of VCM which is a known carcinogenic substance. However, the production of VCM is very tightly regulated so that the results in Figure 18 must all be below the legal limits. Again, this is never mentioned and is misleading for the reader. However, the reader is reminded at this point

> *"that the USEtox database does not contain data for the dioxin emissions"*,

leading the reader to believe that the health impacts of PVC are higher than presented. This again suggests a bias against PVC.

The significance and the meaning of the HH results are never explained or put into perspective. For example, it is not clear how significant is $0.3x10^{-9}$ DALYs for PVC "controlled" in Figure 15 or $1.6x10^{-11}$ "cases" (also, cases of what?) per bag in Figure 18 or $1.3x10^{-6}$ (no units?) in Figure 19. This is not helpful to the reader as it is difficult to interpret these results.

There is a wide range of DEHP leakage values during blood transfusion (14-600 mg for adults). The study has used the value of 328 mg but it is not explained why this value in particular (as it does not represent an average between the low and the high value). A sensitivity analysis should have also been carried out to cover the lowest and highest values.

Furthermore, as DEHP is widely dispersed in the environment, the ambient environmental exposure should have been considered in addition to the exposure from PVC medical devices when assessing the risk of DEHP to human health. This is also clearly stated in the reference used in the LCA study for the assumptions on leakage of DEHP from the PVC bags (http://www.chemicalspolicy.org/downloads/DEHP.pdf, pg 3 – this reference is listed in the LCA report under *References for the LCI database, Use.)* Apart from being scientifically flawed, the results excluding the ambient exposure can be misleading for the reader. The latter also applies to the following assertion (pg 31):

"It is likely that the potential impact induced by blood transfusion is several exponents higher than what is shown in the figures used here due to such aspects."

The rationale for this statement is not explained and no references are quoted in support. The same reference that the authors cite (see above), quotes in the table on page 2 that the exposure rate for infants is 0.8-4.2 mg/kg body weight and for adults 0.2-8.0 kg/body weight. Although the sensitivity of infants is expected to be much higher than that of the adults, judging by these figures, the difference would not be expected to be *"several exponents"* or orders of magnitude as asserted in the above statement. In any case, such speculative and scientifically unsupported statements should be avoided as they indicate either a bias or may be interpreted as scaremongering.

The assumptions on the leakage and uptake of DEHP in blood discussed in the section "The transformation between impact assessment models and risk models" seem arbitrary and made up by the authors of the study as no references are quoted. The authors themselves acknowledge that (pg 31):

"Other assumptions may be made to end up with a different result."

Such an approach is again unscientific and should be avoided.

The Plastics Europe data show that the carcinogenic health impacts of HDPE production are higher than that of PVC (estimated using Ecoindicator 99 and applying the Hierarchist perspective with the "average weighting" method). The results are 2.05×10^{-8} DALYs for HDPE and 1.74×10^{-8} DALYs for PVC. The study should have mentioned and commented on this. Furthermore, these results seem in contradiction to the results in Figure 15, whereby the life cycle results for HDPE appear to be well below the values for the production of HDPE resin, which is obviously not possible. However, it is not possible to tell what the value for HDPE is as the source data in Table D7 are presented in such a way that it is not possible to cross-check the results in Figure 15. This again does not help towards the transparency of the study.

Moreover, as commented previously, the study uses only three environmental impacts to compare the two type of blood bags. This is not enough to make informed and balanced recommendations for the use of one or another type of the bag as the information is far too limited. A full range of impacts should have been used to show how the blood bags compare across all the categories. For example, the Europe Plastics data show that the life cycle of HDPE from 'cradle to gate' (up to and including the granulate production) has higher acidification and freshwater toxicity potentials than the PVC resin (using the suspension polymerisation process, the same one assumed in the LCA study). Their respective values, calculated using the data from the Plastics Europe data in the Ecoinvent database and the CML 2 impact assessment method are shown below:

	Acidification [kg SO_2 eq.]	Freshwater Aquatic Eco-toxicity [kg DCB eq.]
HDPE granulate (Data: Plastics Europe)	4.09×10^{-3}	7.36×10^{-3}
PVC granulate (suspension) (Data: Plastics Europe)	4.06×10^{-3}	4.96×10^{-3}

Furthermore, the study puts a lot of emphasis on the health impacts without considering or discussing the large uncertainties associated with these estimates, particularly as the methodology for estimating health impacts is still in development.

Conclusions for Human Health Impacts

- **It is difficult to interpret the results for health impacts and check their validity as the assumptions are unclear or unjustified and the results have not been explained or put into perspective.**
- **The study puts a lot of emphasis on the health impacts without considering or discussing the large uncertainties associated with these estimates, particularly as the methodology for estimating health impacts is still in development.**
- **The results for the PVC "uncontrolled waste incineration" scenario should be interpreted with care as it is not clear what assumptions have been made with respect to dioxin emissions.**
- **The assumptions on the leakage and uptake of DEHP appear to be arbitrary as they are not supported by evidence or published references.**
- **The results related to the impacts from DEHP should be interpreted with caution as they do not take into account ambient exposure.**
- **The discussion of the health impact results appears to be biased.**

Natural resources

The following statement is unsupported by any facts or references (section 4.4.1, pg 32):

> *"... propose that any actual choice of blood bag should be produced by the most sustainable option, that is non-fossil raw material."*

While the use of such (bio) resources reduces the use of abiotic resources, other impacts can be much higher (e.g. acidification, eutrophication etc.).

Using more efficient production data for PVC, DEHP, HDPE and electricity

It is stated that (pg 33):

> *"However, it was considered more relevant to establish an understanding of the key impact areas of consideration for the blood bags, and to quantify the different impacts and present them, than to have the latest data for all technologies.".*

This is not justifiable and goes against a normal approach in LCA. It is always preferable to use the latest data in LCA as they reflect the actual rather than historical situation and besides, the key areas for consideration may well change with different data used.

Conclusion for Natural Resources:

- **Some of the assumptions and statements in this section are unjustified or unjustifiable.**

2.4. Other comments (Executive summary of the report)

It is stated in the Executive summary that:

> *"The three main environmental impact categories of a PVC/DEHP blood bag are climate change, impact on human health and resource use. Therefore the environmental impact assessment was focusing on these three impact categories.*

This has not been justified or explained either in the Executive summary or anywhere else in the report and yet the whole study is based on this premise.

The results in the Executive summary are presented in a way which suggests a bias against PVC. For example, although PVC is better than HDPE for two out of three impacts considered (climate change and natural resources), the summary starts by saying that PVC is much worse than HDPE for the third impact (human health):

> *"The result of the LCA is that the PVC/DEHP blood bag has a substantially higher potential to harm human health, both when analyzing the total life cycle of the blood bags and with regards to the DEHP contamination of transfused blood."*

At the same time, it is stated that HDPE only has "potentially" higher impacts than PVC:

> *"The HDPE blood bag show a potentially higher impact on resource depletion and climate change."*

The reference to the "huge amount" of DEHP in the following statement is non-specific and is not supported by any references:

> *"This is due to the direct exposure of a huge amount of the toxic phthalate DEHP within the blood stream of patients."*

The Executive summary concludes by asserting that:

> *"The unambiguous recommendation from this study is to change from the PVC/DEHP blood bag towards a blood bag based on only hydrocarbons."*

It is not clear why the recommendation should be "unambiguous" as PVC blood bags are better for two out of the three impacts considered in the study.

Conclusion for the Executive Summary of the LCA Report:

- **The Executive summary appears to be biased against PVC and the results are presented in a way which may be misleading to the reader.**

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