Preliminary Opinion on the safety of the use of bisphenol A in medical devices

Fields marked with * are mandatory.

Personal information

Last Name
Amaral

First name
Maria José

Organisation/company
HCWH Europe

E-mail
maria.jose@hcwh.org

Country
- Afghanistan
- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia
- Bosnia-Herzegovina
- Botswana
- Bouvet Island
- Brazil
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo, Democratic Republic of the (Zaire)
- Congo, Republic of
- Cook Islands
- Costa Rica
- Croatia
- Cuba
- Cyprus
- Czech Republic
- Denmark
- Djibouti
- Dominica
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- Gabon
- Gambia
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe (French)
- Guam (USA)
- Guatemala
- Guinea
- Guinea Bissau
- Guyana
- Haiti
- Holy See
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
Ireland
Israel
Italy
Ivory Coast (Cote D’Ivoire)
Jamaica
Japan
Jordan
Kazakhstan
Kenya
Kiribati
Kuwait
Kyrgyzstan
Laos
Latvia
Lebanon
Lesotho
Liberia
Libya
Liechtenstein
Lithuania
Luxembourg
Macau
Macedonia
Madagascar
Malawi
Malaysia
Maldives
Mali
Malta
Marshall Islands
Martinique (French)
Mauritania
Mauritius
Mayotte
Mexico
Micronesia
Moldova
Monaco
Mongolia
Montenegro
Montserrat
Morocco
Mozambique
Myanmar
Namibia
Nauru
Nepal
Netherlands
Netherlands Antilles
New Caledonia (French)
New Zealand
Nicaragua
Niger
Nigeria
Niue
Norfolk Island
North Korea
Northern Mariana Islands
Norway
Oman
Pakistan
Palau
Panama
Papua New Guinea
Paraguay
Peru
Philippines
Pitcairn Island
Poland
Polynesia (French)
Portugal
Puerto Rico
Qatar
Reunion
Romania
Russia
Rwanda
Saint Helena
Saint Kitts and Nevis
Saint Lucia
Saint Pierre and Miquelon
Saint Vincent and Grenadines
Samoa
San Marino
Sao Tome and Principe
Saudi Arabia
Senegal
Serbia
Seychelles
Sierra Leone
Singapore
Slovakia
Slovenia
Solomon Islands
Somalia
South Africa
South Georgia and South Sandwich Islands
South Korea
South Sudan
Spain
Sri Lanka
Sudan
Suriname
Svalbard and Jan Mayen Islands
Swaziland
Sweden
Switzerland
Syria
Taiwan
Tajikistan
Tanzania
Thailand
Timor-Leste (East Timor)
Togo
Tokelau
Tonga
Trinidad and Tobago
Tunisia
Turkey
Turkmenistan
Turks and Caicos Islands
Tuvalu
Uganda
Ukraine
United Arab Emirates
United Kingdom
Chapter/section

If you have comments on different chapters/sections, please select the chapter, add your comment, and submit your comments separately. Please also upload the scientific papers you consider relevant for that section/chapter. Repeat this operation for each chapter you would like to comment on. After sending a comment, it will be indicated if it has been sent successfully and you will be able to enter your next comment.

Table of content

1. BACKGROUND
2. TERMS OF REFERENCE
3. SCIENTIFIC RATIONALE
   3.1. Introduction
   3.2. Methodology
   3.3. Chemistry of BPA
   3.4. Physico-Chemical Properties
   3.5. Overview of existing assessments on BPA
      3.5.1. Existing assessments
      3.5.2. Controversial issues
      3.5.3. Conclusion
   3.6. Identification of the relevant medical devices
      3.6.1. Medical devices
      3.6.2. Presence in and release of BPA from medical devices
      3.6.3. Conclusions
   3.7. Exposure scenarios
      3.7.1. Knowledge on BPA exposure
         3.7.1.1. Methods for measurement of internal exposure in humans
         3.7.1.2. Internal exposure to BPA in humans from all routes
3.7.1.3. Non-oral exposure routes
3.7.2. Exposure to BPA from medical devices
3.7.3. Exposure to BPA from medical devices under different scenarios
3.7.4. BPA exposure from uses of BPA containing PVC
3.7.5. Conclusions
3.8. Toxicokinetics of bisphenol A
3.8.1. BPA biotransformation
3.8.2. Toxicokinetics after oral uptake
3.8.3. Toxicokinetics after uptake by other routes
3.8.3.1. Toxicokinetics after dermal and transcutaneous uptake
3.8.3.2. Toxicokinetics after intravenous administration
3.8.3.3. Toxicokinetics after inhalation
3.8.4. Special considerations on susceptible populations
3.8.5. Conclusions
3.9. Toxicity
3.9.1. General toxicity studies
3.9.1.1. Acute toxicity
3.9.1.2. Chronic toxicity (repeated-dose) studies
3.9.2. Genotoxicity
3.9.3. Carcinogenicity
3.9.4. Neurotoxicity and behavioural toxicity
3.9.5. Immunotoxicity
3.9.6. Cardiovascular effects
3.9.7. Metabolic disorders
3.9.8. Reproductive and developmental toxicity
3.9.9. Conclusions on toxicity
3.10. Epidemiological studies
3.11. Alternatives to BPA currently use
3.12. Recommendations for research

4. OPINION
5. MINORITY OPINION
6. LIST OF ABBREVIATIONS
7. REFERENCES
8. ANNEXES

Please indicate the line numbers of the text on which you comment, if appropriate.

2,500 character(s) maximum

L9 - The concept of BPA as a weak oestrogen has been challenged by several authors see for example Wozniak et al. 2005 Environmental Health Perspectives 113: 431-439.
Please upload your file (max. 1 Mo per file)

1. 132ae4e6-3941-438d-98fd-cd57b780a064/Wozniak_2005_Environmental_Health_Perspectives.pdf

Privacy statement

Read the Privacy Statement*

- I do not object to publication of my contribution, including my personal data, on internet
- I do object to publication of my contribution, including my personal data on internet to
  the grounds that such publication would harm my legitimate interests
Chapter/section

If you have comments on different chapters/sections, please select the chapter, add your comment, and submit your comments separately. Please also upload the scientific papers you consider relevant for that section/chapter. Repeat this operation for each chapter you would like to comment on. After sending a comment, it will be indicated if it has been sent successfully and you will be able to enter your next comment.

Table of content

- 1. BACKGROUND
- 2. TERMS OF REFERENCE
- 3. SCIENTIFIC RATIONALE
  - 3.1. Introduction
  - 3.2. Methodology
  - 3.3. Chemistry of BPA
  - 3.4. Physico-Chemical Properties
  - 3.5. Overview of existing assessments on BPA
    - 3.5.1. Existing assessments
    - 3.5.2. Controversial issues
    - 3.5.3. Conclusion
  - 3.6. Identification of the relevant medical devices
    - 3.6.1. Medical devices
    - 3.6.2. Presence in and release of BPA from medical devices
    - 3.6.3. Conclusions
  - 3.7. Exposure scenarios
    - 3.7.1. Knowledge on BPA exposure
      - 3.7.1.1. Methods for measurement of internal exposure in humans
      - 3.7.1.2. Internal exposure to BPA in humans from all routes
3.7.1.3. Non-orally exposure routes
3.7.2. Exposure to BPA from medical devices
3.7.3. Exposure to BPA from medical devices under different scenarios
3.7.4. BPA exposure from uses of BPA containing PVC
3.7.5. Conclusions
3.8. Toxicokinetics of bisphenol A
3.8.1. BPA biotransformation
3.8.2. Toxicokinetics after oral uptake
3.8.3. Toxicokinetics after uptake by other routes
3.8.3.1. Toxicokinetics after dermal and transcutaneous uptake
3.8.3.2. Toxicokinetics after intravenous administration
3.8.3.3. Toxicokinetics after inhalation
3.8.4. Special considerations on susceptible populations
3.8.5. Conclusions
3.9. Toxicity
3.9.1. General toxicity studies
3.9.1.1. Acute toxicity
3.9.1.2. Chronic toxicity (repeated-dose) studies
3.9.2. Genotoxicity
3.9.3. Carcinogenicity
3.9.4. Neurotoxicity and behavioural toxicity
3.9.5. Immunotoxicity
3.9.6. Cardiovascular effects
3.9.7. Metabolic disorders
3.9.8. Reproductive and developmental toxicity
3.9.9. Conclusions on toxicity
3.10. Epidemiological studies
3.11. Alternatives to BPA currently use
3.12. Recommendations for research

4. OPINION
5. MINORITY OPINION
6. LIST OF ABBREVIATIONS
7. REFERENCES
8. ANNEXES

Please indicate the line numbers of the text on which you comment, if appropriate.

2,500 character(s) maximum

L31-33 How was SCENIHR able to assess clinical benefit of the medical devices in consideration? Clinical benefit is evaluated during the authorisation process for a specific product. It should not be taken lightly by SCENIHR, which is only a scientific consultation group.
Please upload your file (max. 1 Mo per file)

Privacy statement

Read the Privacy Statement *

- [ ] I do not object to publication of my contribution, including my personal data, on internet
- [ ] I do object to publication of my contribution, including my personal data on internet to the grounds that such publication would harm my legitimate interests
Chapter/section

If you have comments on different chapters/sections, please select the chapter, add your comment, and submit your comments separately. Please also upload the scientific papers you consider relevant for that section/chapter. Repeat this operation for each chapter you would like to comment on. After sending a comment, it will be indicated if it has been sent successfully and you will be able to enter your next comment.

Table of content

- 1. BACKGROUND
- 2. TERMS OF REFERENCE
- 3. SCIENTIFIC RATIONALE
  - 3.1. Introduction
  - 3.2. Methodology
  - 3.3. Chemistry of BPA
  - 3.4. Physico-Chemical Properties
  - 3.5. Overview of existing assessments on BPA
    - 3.5.1. Existing assessments
    - 3.5.2. Controversial issues
    - 3.5.3. Conclusion
  - 3.6. Identification of the relevant medical devices
    - 3.6.1. Medical devices
    - 3.6.2. Presence in and release of BPA from medical devices
    - 3.6.3. Conclusions
  - 3.7. Exposure scenarios
    - 3.7.1. Knowledge on BPA exposure
      - 3.7.1.1. Methods for measurement of internal exposure in humans
      - 3.7.1.2. Internal exposure to BPA in humans from all routes
3.7.1.3. Non-oral exposure routes
3.7.2. Exposure to BPA from medical devices
3.7.3. Exposure to BPA from medical devices under different scenarios
3.7.4. BPA exposure from uses of BPA containing PVC
3.7.5. Conclusions
3.8. Toxicokinetics of bisphenol A
3.8.1. BPA biotransformation
3.8.2. Toxicokinetics after oral uptake
3.8.3. Toxicokinetics after uptake by other routes
3.8.3.1. Toxicokinetics after dermal and transcutaneous uptake
3.8.3.2. Toxicokinetics after intravenous administration
3.8.3.3. Toxicokinetics after inhalation
3.8.4. Special considerations on susceptible populations
3.8.5. Conclusions
3.9. Toxicity
3.9.1. General toxicity studies
3.9.1.1. Acute toxicity
3.9.1.2. Chronic toxicity (repeated-dose) studies
3.9.2. Genotoxicity
3.9.3. Carcinogenicity
3.9.4. Neurotoxicity and behavioural toxicity
3.9.5. Immunotoxicity
3.9.6. Cardiovascular effects
3.9.7. Metabolic disorders
3.9.8. Reproductive and developmental toxicity
3.9.9. Conclusions on toxicity
3.10. Epidemiological studies
3.11. Alternatives to BPA currently use
3.12. Recommendations for research

4. OPINION
5. MINORITY OPINION
6. LIST OF ABBREVIATIONS
7. REFERENCES
8. ANNEXES
The presence of BPA in PVC medical devices is not well addressed in the opinion. One one side, the opinion is relying exclusively in information provided by the industry, that BPA is not longer used in the production of PVC by European PVC manufacturers. This information should be verified by an independent regulatory body. For example, in the case of CMR phthalates in toys, that are regulated by EU law, the Swedish chemicals regulatory agency found several products in the market that did not comply with the law. On the other side, even accepting the claim as correct for the European PVC manufacturers, this means very little on the global medical device market. The opinion neglects that both medical devices manufacturers and medical devices procurers have suppliers outside of the European market, where PVC containing BPA can still be the norm. For example, 10 million surgical interments used each year by NHS UK are manufactured in Pakistan. Furthermore, many of the main European manufacturers of medical devices admit they cannot enquire their manufacturers if a certain chemical has been added or not (for further information see Green Public Procurement criteria for BPA in medical devices). The issue of PVC medical devices containing BPA is of high concern, as most of these medical devices are used to provide intravenously solutions to patients, where the problem of migration of the plastic material and leaching is greatest. Finally, BPA is also used in the production of polycrylates used in coating of medical devices, and in polyetherimide plastics like sterilisation trays and dentist devices.
Preliminary Opinion on the safety of the use of bisphenol A in medical devices

Fields marked with * are mandatory.

Personal information

Last Name
Amaral

First name
Maria José

Organisation/company
HCWH Europe

E-mail
maria.jose@hcwh.org

Country
- Afghanistan
- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Denmark
- Djibouti
- Dominica
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- Gabon
- Gambia
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe (French)
- Guam (USA)
- Guatemala
- Guinea
- Guinea Bissau
- Guyana
- Haiti
- Holy See
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
Mozambique
Myanmar
Namibia
Nauru
Nepal
Netherlands
Netherlands Antilles
New Caledonia (French)
New Zealand
Nicaragua
Niger
Nigeria
Niue
Norfolk Island
North Korea
Northern Mariana Islands
Norway
Oman
Pakistan
Palau
Panama
Papua New Guinea
Paraguay
Peru
Philippines
Pitcairn Island
Poland
Polynesia (French)
Portugal
Puerto Rico
Qatar
Reunion
Romania
Russia
Rwanda
Saint Helena
Saint Kitts and Nevis
Saint Lucia
Saint Pierre and Miquelon
Saint Vincent and Grenadines
Samoa
San Marino
- Sao Tome and Principe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen Islands
- Swaziland
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- Timor-Leste (East Timor)
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
Chapter/section

If you have comments on different chapters/sections, please select the chapter, add your comment, and submit your comments separately. Please also upload the scientific papers you consider relevant for that section/chapter. Repeat this operation for each chapter you would like to comment on. After sending a comment, it will be indicated if it has been sent successfully and you will be able to enter your next comment.

Table of content

1. BACKGROUND
2. TERMS OF REFERENCE
3. SCIENTIFIC RATIONALE
   3.1. Introduction
   3.2. Methodology
   3.3. Chemistry of BPA
   3.4. Physico-Chemical Properties
   3.5. Overview of existing assessments on BPA
      3.5.1. Existing assessments
      3.5.2. Controversial issues
      3.5.3. Conclusion
   3.6. Identification of the relevant medical devices
      3.6.1. Medical devices
      3.6.2. Presence in and release of BPA from medical devices
      3.6.3. Conclusions
   3.7. Exposure scenarios
      3.7.1. Knowledge on BPA exposure
      3.7.1.1. Methods for measurement of internal exposure in humans
      3.7.1.2. Internal exposure to BPA in humans from all routes
3.7.1.3. Non-oral exposure routes
3.7.2. Exposure to BPA from medical devices
3.7.3. Exposure to BPA from medical devices under different scenarios
3.7.4. BPA exposure from uses of BPA containing PVC
3.7.5. Conclusions
3.8. Toxicokinetics of bisphenol A
3.8.1. BPA biotransformation
3.8.2. Toxicokinetics after oral uptake
3.8.3. Toxicokinetics after uptake by other routes
3.8.3.1. Toxicokinetics after dermal and transcutaneous uptake
3.8.3.2. Toxicokinetics after intravenous administration
3.8.3.3. Toxicokinetics after inhalation
3.8.4. Special considerations on susceptible populations
3.8.5. Conclusions
3.9. Toxicity
3.9.1. General toxicity studies
3.9.1.1. Acute toxicity
3.9.1.2. Chronic toxicity (repeated-dose) studies
3.9.2. Genotoxicity
3.9.3. Carcinogenicity
3.9.4. Neurotoxicity and behavioural toxicity
3.9.5. Immunotoxicity
3.9.6. Cardiovascular effects
3.9.7. Metabolic disorders
3.9.8. Reproductive and developmental toxicity
3.9.9. Conclusions on toxicity
3.10. Epidemiological studies
3.11. Alternatives to BPA currently use
3.12. Recommendations for research
4. OPINION
5. MINORITY OPINION
6. LIST OF ABBREVIATIONS
7. REFERENCES
8. ANNEXES

Please indicate the line numbers of the text on which you comment, if appropriate.

2,500 character(s) maximum

L31-33 How was SCENIHR able to assess clinical benefit of the medical devices in consideration? Clinical benefit is evaluated during the authorisation process for a specific product. It should not be taken lightly by SCENIHR, which is only a scientific consultation group.
Please upload your file (max. 1 Mo per file)

Privacy statement

Read the Privacy Statement*

- I do not object to publication of my contribution, including my personal data, on internet
- I do object to publication of my contribution, including my personal data on internet to the grounds that such publication would harm my legitimate interests
Preliminary Opinion on the safety of the use of bisphenol A in medical devices

Fields marked with * are mandatory.

**Personal information**

Last Name

Amaral

First name

Maria José

Organisation/company

HCWH Europe

E-mail

maria.jose@hcwh.org

Country

- Afghanistan
- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
Austria
Azerbaijan
Bahamas
Bahrain
Bangladesh
Barbados
Belarus
Belgium
Belize
Benin
Bermuda
Bhutan
Bolivia
Bosnia-Herzegovina
Botswana
Bouvet Island
Brazil
Brunei
Bulgaria
Burkina Faso
Burundi
Cambodia
Cameroon
Canada
Cape Verde
Cayman Islands
Central African Republic
Chad
Chile
China
Christmas Island
Cocos (Keeling) Islands
Colombia
Comoros
Congo, Democratic Republic of the (Zaire)
Congo, Republic of
Cook Islands
Costa Rica
Croatia
Cuba
Cyprus
Czech Republic
Denmark
Djibouti
Dominica
Dominican Republic
Ecuador
Egypt
El Salvador
Equatorial Guinea
Eritrea
Estonia
Ethiopia
Falkland Islands
Faroe Islands
Fiji
Finland
France
French Guiana
Gabon
Gambia
Georgia
Germany
Ghana
Gibraltar
Greece
Greenland
Grenada
Guadeloupe (French)
Guam (USA)
Guatemala
Guinea
Guinea Bissau
Guyana
Haiti
Holy See
Honduras
Hong Kong
Hungary
Iceland
India
Indonesia
Iran
Iraq
Sao Tome and Principe
Saudi Arabia
Senegal
Serbia
Seychelles
Sierra Leone
Singapore
Slovakia
Slovenia
Solomon Islands
Somalia
South Africa
South Georgia and South Sandwich Islands
South Korea
South Sudan
Spain
Sri Lanka
Sudan
Suriname
Svalbard and Jan Mayen Islands
Swaziland
Sweden
Switzerland
Syria
Taiwan
Tajikistan
Tanzania
Thailand
Timor-Leste (East Timor)
Togo
Tokelau
Tonga
Trinidad and Tobago
Tunisia
Turkey
Turkmenistan
Turks and Caicos Islands
Tuvalu
Uganda
Ukraine
United Arab Emirates
United Kingdom
Chapter/section

If you have comments on different chapters/sections, please select the chapter, add your comment, and submit your comments separately. Please also upload the scientific papers you consider relevant for that section/chapter. Repeat this operation for each chapter you would like to comment on. After sending a comment, it will be indicated if it has been sent successfully and you will be able to enter your next comment.

Table of content

- **1. BACKGROUND**
- **2. TERMS OF REFERENCE**
- **3. SCIENTIFIC RATIONALE**
  - 3.1. Introduction
  - 3.2. Methodology
  - 3.3. Chemistry of BPA
  - 3.4. Physico-Chemical Properties
  - 3.5. Overview of existing assessments on BPA
    - 3.5.1. Existing assessments
    - 3.5.2. Controversial issues
    - 3.5.3. Conclusion
  - 3.6. Identification of the relevant medical devices
    - 3.6.1. Medical devices
    - 3.6.2. Presence in and release of BPA from medical devices
    - 3.6.3. Conclusions
  - 3.7. Exposure scenarios
    - 3.7.1. Knowledge on BPA exposure
      - 3.7.1.1. Methods for measurement of internal exposure in humans
      - 3.7.1.2. Internal exposure to BPA in humans from all routes
3.7.1.3. Non-oral exposure routes
3.7.2. Exposure to BPA from medical devices
3.7.3. Exposure to BPA from medical devices under different scenarios
3.7.4. BPA exposure from uses of BPA containing PVC
3.7.5. Conclusions
3.8. Toxicokinetics of bisphenol A
3.8.1. BPA biotransformation
3.8.2. Toxicokinetics after oral uptake
3.8.3. Toxicokinetics after uptake by other routes
3.8.3.1. Toxicokinetics after dermal and transcutaneous uptake
3.8.3.2. Toxicokinetics after intravenous administration
3.8.3.3. Toxicokinetics after inhalation
3.8.4. Special considerations on susceptible populations
3.8.5. Conclusions
3.9. Toxicity
3.9.1. General toxicity studies
3.9.1.1. Acute toxicity
3.9.1.2. Chronic toxicity (repeated-dose) studies
3.9.2. Genotoxicity
3.9.3. Carcinogenicity
3.9.4. Neurotoxicity and behavioural toxicity
3.9.5. Immunotoxicity
3.9.6. Cardiovascular effects
3.9.7. Metabolic disorders
3.9.8. Reproductive and developmental toxicity
3.9.9. Conclusions on toxicity
3.10. Epidemiological studies
3.11. Alternatives to BPA currently use
3.12. Recommendations for research

4. OPINION
5. MINORITY OPINION
6. LIST OF ABBREVIATIONS
7. REFERENCES
8. ANNEXES
Health Care Without Harm Europe has been involved for many years in the promotion of safer medical devices without hazardous chemicals, as part of the solution to a non-toxic healthcare sector. Recently, we launched a fact sheet on Bisphenol A in medical devices and an online database to help healthcare staff to help identify alternatives to medical devices containing PVC or phthalates, which we hope to expand to BPA-free medical devices in the near future. HCWH Europe disagrees with the approach of the SCENIHR and asks for an interpretation of scientific uncertainty in favor of a precautionary approach rather than inaction and regulatory business as usual. In particular for vulnerable groups like premature infants and dialysis patients, which have developing or impaired organs unable to metabolise efficiently BPA into a safe metabolite. Furthermore, we are exposed to a variety of environmental toxicants on our daily life and effects of exposure to BPA cannot be looked at individually, as the substances can have cumulative and mixture effects. HCWH Europe also disagrees with the position SCENIHR takes on the benefit analysis, BPA content on PVC products, the safeness of EFSA toxicological values, the reproductive toxic effects and the overwhelming consistency of results from epidemiological studies. The benefit analysis is already performed during the market authorisation of the devices. Is not the goal of this opinion to discourse on that, as the Committee does not have enough information about the medical efficiency of each and all-medical device under scrutiny. The opinion relies on claims of European manufacturers of PVC, that BPA is no longer used as an additive to PVC and completely ignoring that many medical devices manufacturers and procurers obtain their raw material or products in other markets outside EU. The opinion also grossly overlooks important information from the ANSES report, that has lead to the calculation of toxicological reference values much lower than the Adult Daily Intake values defended by EFSA and to a request from France, recently adopted in an ECHA committee, to raise the CMR category of BPA to R2 due to the strong evidence of reproductive toxicity from animal studies. Finally, the opinion neglects or dismisses the consistency over different populations and age groups of epidemiological studies that have associated BPA exposure with a variety of disease conditions.
Preliminary Opinion on the safety of the use of bisphenol A in medical devices

Fields marked with * are mandatory.

Personal information

Last Name
Amaral

First name
Maria José

Organisation/company
HCWH Europe

E-mail
maria.jose@hcwh.org

Country
- Afghanistan
- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
Denmark
Djibouti
Dominica
Dominican Republic
Ecuador
Egypt
El Salvador
Equatorial Guinea
Eritrea
Estonia
Ethiopia
Falkland Islands
Faroe Islands
Fiji
Finland
France
French Guiana
Gabon
Gambia
Georgia
Germany
Ghana
Gibraltar
Greece
Greenland
Grenada
Guadeloupe (French)
Guam (USA)
Guatemala
Guinea
Guinea Bissau
Guyana
Haiti
Holy See
Honduras
Hong Kong
Hungary
Iceland
India
Indonesia
Iran
Iraq
Ireland
Israel
Italy
Ivory Coast (Cote D'Ivoire)
Jamaica
Japan
Jordan
Kazakhstan
Kenya
Kiribati
Kuwait
Kyrgyzstan
Laos
Latvia
Lebanon
Lesotho
Liberia
Libya
Liechtenstein
Lithuania
Luxembourg
Macau
Macedonia
Madagascar
Malawi
Malaysia
Maldives
Mali
Malta
Marshall Islands
Martinique (French)
Mauritania
Mauritius
Mayotte
Mexico
Micronesia
Moldova
Monaco
Mongolia
Montenegro
Montserrat
Morocco
Mozambique
Myanmar
Namibia
Nauru
Nepal
Netherlands
Netherlands Antilles
New Caledonia (French)
New Zealand
Nicaragua
Niger
Nigeria
Niue
Norfolk Island
North Korea
Northern Mariana Islands
Norway
Oman
Pakistan
Palau
Panama
Papua New Guinea
Paraguay
Peru
Philippines
Pitcairn Island
Poland
Polynesia (French)
Portugal
Puerto Rico
Qatar
Reunion
Romania
Russia
Rwanda
Saint Helena
Saint Kitts and Nevis
Saint Lucia
Saint Pierre and Miquelon
Saint Vincent and Grenadines
Samoa
San Marino
- Sao Tome and Principe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen Islands
- Swaziland
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- Timor-Leste (East Timor)
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
Chapter/section

If you have comments on different chapters/sections, please select the chapter, add your comment, and submit your comments separately. Please also upload the scientific papers you consider relevant for that section/chapter. Repeat this operation for each chapter you would like to comment on. After sending a comment, it will be indicated if it has been sent successfully and you will be able to enter your next comment.

Table of content

1. BACKGROUND
2. TERMS OF REFERENCE
3. SCIENTIFIC RATIONALE
   3.1. Introduction
   3.2. Methodology
   3.3. Chemistry of BPA
   3.4. Physico-Chemical Properties
   3.5. Overview of existing assessments on BPA
      3.5.1. Existing assessments
      3.5.2. Controversial issues
      3.5.3. Conclusion
   3.6. Identification of the relevant medical devices
      3.6.1. Medical devices
      3.6.2. Presence in and release of BPA from medical devices
      3.6.3. Conclusions
   3.7. Exposure scenarios
      3.7.1. Knowledge on BPA exposure
      3.7.1.1. Methods for measurement of internal exposure in humans
      3.7.1.2. Internal exposure to BPA in humans from all routes
3.7.1.3. Non-oral exposure routes
3.7.2. Exposure to BPA from medical devices
3.7.3. Exposure to BPA from medical devices under different scenarios
3.7.4. BPA exposure from uses of BPA containing PVC
3.7.5. Conclusions
3.8. Toxicokinetics of bisphenol A
3.8.1. BPA biotransformation
3.8.2. Toxicokinetics after oral uptake
3.8.3. Toxicokinetics after uptake by other routes
3.8.3.1. Toxicokinetics after dermal and transcutaneous uptake
3.8.3.2. Toxicokinetics after intravenous administration
3.8.3.3. Toxicokinetics after inhalation
3.8.4. Special considerations on susceptible populations
3.8.5. Conclusions
3.9. Toxicity
3.9.1. General toxicity studies
3.9.1.1. Acute toxicity
3.9.1.2. Chronic toxicity (repeated-dose) studies
3.9.2. Genotoxicity
3.9.3. Carcinogenicity
3.9.4. Neurotoxicity and behavioural toxicity
3.9.5. Immunotoxicity
3.9.6. Cardiovascular effects
3.9.7. Metabolic disorders
3.9.8. Reproductive and developmental toxicity
3.9.9. Conclusions on toxicity
3.10. Epidemiological studies
3.11. Alternatives to BPA currently use
3.12. Recommendations for research
4. OPINION
5. MINORITY OPINION
6. LIST OF ABBREVIATIONS
7. REFERENCES
8. ANNEXES

Please indicate the line numbers of the text on which you comment, if appropriate.

2,500 character(s) maximum

The list of current alternatives is not complete, other materials currently being used as alternatives for BPA include polymethylmethacrylate, copolyester, polypropylene, triacetate. In the case of PVC products, several PVC free alternatives are also available in the market (see www.safermedicaldevices.org for examples of PVC free alternatives in the market and alternative materials).
Privacy statement

Read the Privacy Statement

☐ I do not object to publication of my contribution, including my personal data, on internet
☐ I do object to publication of my contribution, including my personal data on internet to the grounds that such publication would harm my legitimate interests
Preliminary Opinion on the safety of the use of bisphenol A in medical devices

Fields marked with * are mandatory.

Personal information

Last Name
Amaral

First name
Maria José

Organisation/company
HCWH Europe

E-mail
maria.jose@hcwh.org

Country
- Afghanistan
- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Denmark
- Djibouti
- Dominica
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- Gabon
- Gambia
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe (French)
- Guam (USA)
- Guatemala
- Guinea
- Guinea Bissau
- Guyana
- Haiti
- Holy See
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
Mozambique
Myanmar
Namibia
Nauru
Nepal
Netherlands
Netherlands Antilles
New Caledonia (French)
New Zealand
Nicaragua
Niger
Nigeria
Niue
Norfolk Island
North Korea
Northern Mariana Islands
Norway
Oman
Pakistan
Palau
Panama
Papua New Guinea
Paraguay
Peru
Philippines
Pitcairn Island
Poland
Polynesia (French)
Portugal
Puerto Rico
Qatar
Reunion
Romania
Russia
Rwanda
Saint Helena
Saint Kitts and Nevis
Saint Lucia
Saint Pierre and Miquelon
Saint Vincent and Grenadines
Samoa
San Marino
Sao Tome and Principe
Saudi Arabia
Senegal
Serbia
Seychelles
Sierra Leone
Singapore
Slovakia
Slovenia
Solomon Islands
Somalia
South Africa
South Georgia and South Sandwich Islands
South Korea
South Sudan
Spain
Sri Lanka
Sudan
Suriname
Svalbard and Jan Mayen Islands
Swaziland
Sweden
Switzerland
Syria
Taiwan
Tajikistan
Tanzania
Thailand
Timor-Leste (East Timor)
Togo
Tokelau
Tonga
Trinidad and Tobago
Tunisia
Turkey
Turkmenistan
Turks and Caicos Islands
Tuvalu
Uganda
Ukraine
United Arab Emirates
United Kingdom
If you have comments on different chapters/sections, please select the chapter, add your comment, and submit your comments separately. Please also upload the scientific papers you consider relevant for that section/chapter. Repeat this operation for each chapter you would like to comment on. After sending a comment, it will be indicated if it has been sent successfully and you will be able to enter your next comment.

Table of content

1. BACKGROUND
2. TERMS OF REFERENCE
3. SCIENTIFIC RATIONALE
   3.1. Introduction
   3.2. Methodology
   3.3. Chemistry of BPA
   3.4. Physico-Chemical Properties
   3.5. Overview of existing assessments on BPA
      3.5.1. Existing assessments
      3.5.2. Controversial issues
      3.5.3. Conclusion
   3.6. Identification of the relevant medical devices
      3.6.1. Medical devices
      3.6.2. Presence in and release of BPA from medical devices
      3.6.3. Conclusions
   3.7. Exposure scenarios
      3.7.1. Knowledge on BPA exposure
         3.7.1.1. Methods for measurement of internal exposure in humans
         3.7.1.2. Internal exposure to BPA in humans from all routes
3.7.1.3. Non-oral exposure routes
3.7.2. Exposure to BPA from medical devices
3.7.3. Exposure to BPA from medical devices under different scenarios
3.7.4. BPA exposure from uses of BPA containing PVC
3.7.5. Conclusions
3.8. Toxicokinetics of bisphenol A
3.8.1. BPA biotransformation
3.8.2. Toxicokinetics after oral uptake
3.8.3. Toxicokinetics after uptake by other routes
3.8.3.1. Toxicokinetics after dermal and transcutaneous uptake
3.8.3.2. Toxicokinetics after intravenous administration
3.8.3.3. Toxicokinetics after inhalation
3.8.4. Special considerations on susceptible populations
3.8.5. Conclusions
3.9. Toxicity
3.9.1. General toxicity studies
3.9.1.1. Acute toxicity
3.9.1.2. Chronic toxicity (repeated-dose) studies
3.9.2. Genotoxicity
3.9.3. Carcinogenicity
3.9.4. Neurotoxicity and behavioural toxicity
3.9.5. Immunotoxicity
3.9.6. Cardiovascular effects
3.9.7. Metabolic disorders
3.9.8. Reproductive and developmental toxicity
3.9.9. Conclusions on toxicity
3.10. Epidemiological studies
3.11. Alternatives to BPA currently use
3.12. Recommendations for research
4. OPINION
5. MINORITY OPINION
6. LIST OF ABBREVIATIONS
7. REFERENCES
8. ANNEXES
L50-51 The number of studies considered in the opinion is disappointing. A recent study found 91 peer-reviewed studies linking BPA to human health, 53 published during 2012 so in time to be considered in the opinion see Rochester (2013) Bisphenol A and human health: a review of the literature. Reproductive Toxicology 42: 132-155. The authors of the opinion seem overall more concerned in pointing each and every limitation in the research papers that document effects on human health of BPA exposure than of having a precautionary approach taking in account the consistency and overwhelming amount of evidence provided by many of those studies. The difficulties associated with performing epidemiological studies should not prevent that the trends observed in many studies are valid and that the precautionary principle is put in place. L7-8

Although the three studies have limitations they show consistent results in different populations and strong dose-response effects. L24 Taking in consideration the difficulty of performing human studies, animal studies can provide helpful insights. For both rodents and primates there is ample evidence that prenatal exposure to BPA can cause disruption of the mammary tissue and increased susceptibility to chemical carcinogens. L50-51 Several studies have looked into neurobehavioral effects during gestation. On the whole, the studies strongly suggest that BPA is associated with neurobehavioral problems in children. L3-L12 Many scientific studies have been carried on the bases of the NHANES data, and the results of the different studies are consistent, which strengthens the association between adult BPA exposure and type 2 diabetes and coronary disease. L12-L15 The major limitation pointed to the study - spot urine sample - just implies that BPA exposure might have been in the past more reduced but also higher than the current levels. BPA exposure has been consistently associated across different population groups with different reproductive, metabolic, cardiovascular, immunological and genetic diseases. Most of these results are also supported by in vitro and in vivo animals studies, and should not be disregarded lightly. The precautionary principle clearly states than in the absence of scientific consensus that the burden of proof that it is not harmful falls on those taking action. For all the comments provided in this section please see the attached scientific paper Rochester 2013 and references there in.
Preliminary Opinion on the safety of the use of bisphenol A in medical devices

Fields marked with * are mandatory.

**Personal information**

Last Name
Amaral

First name
Maria José

Organisation/company
HCWH Europe

E-mail
maria.jose@hcwh.org

Country
- Afghanistan
- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
Ireland
Israel
Italy
Ivory Coast (Cote D’Ivoire)
Jamaica
Japan
Jordan
Kazakhstan
Kenya
Kiribati
Kuwait
Kyrgyzstan
Laos
Latvia
Lebanon
Lesotho
Liberia
Libya
Liechtenstein
Lithuania
Luxembourg
Macau
Macedonia
Madagascar
Malawi
Malaysia
Maldive
Mali
Malta
Marshall Islands
Martinique (French)
Mauritania
Mauritius
Mayotte
Mexico
Micronesia
Moldova
Monaco
Mongolia
Montenegro
Montserrat
Morocco
Mozambique
Myanmar
Namibia
Nauru
Nepal
Netherlands
Netherlands Antilles
New Caledonia (French)
New Zealand
Nicaragua
Niger
Nigeria
Niue
Norfolk Island
North Korea
Northern Mariana Islands
Norway
Oman
Pakistan
Palau
Panama
Papua New Guinea
Paraguay
Peru
Philippines
Pitcairn Island
Poland
Polynesia (French)
Portugal
Puerto Rico
Qatar
Reunion
Romania
Russia
Rwanda
Saint Helena
Saint Kitts and Nevis
Saint Lucia
Saint Pierre and Miquelon
Saint Vincent and Grenadines
Samoa
San Marino
- Sao Tome and Principe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen Islands
- Swaziland
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- Timor-Leste (East Timor)
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
United States
Uruguay
Uzbekistan
Vanuatu
Venezuela
Vietnam
Virgin Islands
Wallis and Futuna Islands
Yemen
Zambia
Zimbabwe

Chapter/section

If you have comments on different chapters/sections, please select the chapter, add your comment, and submit your comments separately. Please also upload the scientific papers you consider relevant for that section/chapter. Repeat this operation for each chapter you would like to comment on. After sending a comment, it will be indicated if it has been sent successfully and you will be able to enter your next comment.

Table of content

1. BACKGROUND
2. TERMS OF REFERENCE
3. SCIENTIFIC RATIONALE
   3.1. Introduction
   3.2. Methodology
   3.3. Chemistry of BPA
   3.4. Physico-Chemical Properties
   3.5. Overview of existing assessments on BPA
      3.5.1. Existing assessments
      3.5.2. Controversial issues
      3.5.3. Conclusion
   3.6. Identification of the relevant medical devices
      3.6.1. Medical devices
      3.6.2. Presence in and release of BPA from medical devices
      3.6.3. Conclusions
   3.7. Exposure scenarios
      3.7.1. Knowledge on BPA exposure
         3.7.1.1. Methods for measurement of internal exposure in humans
         3.7.1.2. Internal exposure to BPA in humans from all routes
3.7.3. Exposure to BPA from medical devices under different scenarios
3.7.4. BPA exposure from uses of BPA containing PVC
3.7.5. Conclusions
3.8. Toxicokinetics of bisphenol A
3.8.1. BPA biotransformation
3.8.2. Toxicokinetics after oral uptake
3.8.3. Toxicokinetics after uptake by other routes
3.8.3.1. Toxicokinetics after dermal and transcutaneous uptake
3.8.3.2. Toxicokinetics after intravenous administration
3.8.3.3. Toxicokinetics after inhalation
3.8.4. Special considerations on susceptible populations
3.8.5. Conclusions
3.9. Toxicity
3.9.1. General toxicity studies
3.9.1.1. Acute toxicity
3.9.1.2. Chronic toxicity (repeated-dose) studies
3.9.2. Genotoxicity
3.9.3. Carcinogenicity
3.9.4. Neurotoxicity and behavioural toxicity
3.9.5. Immunotoxicity
3.9.6. Cardiovascular effects
3.9.7. Metabolic disorders
3.9.8. Reproductive and developmental toxicity
3.9.9. Conclusions on toxicity
3.10. Epidemiological studies
3.11. Alternatives to BPA currently use
3.12. Recommendations for research

4. OPINION

5. MINORITY OPINION

6. LIST OF ABBREVIATIONS

7. REFERENCES

8. ANNEXES
In the opinion the SCENIHR chose to not consider gloves in the assessment. This was based on the information provided by the use of BPA in PVC products provided by European PVC manufacturers, mentioned already in a previous comment. Gloves are one of the products where low cost has driven procurers to find cheaper solutions outside of the EU. Moreover, are one of the most consumed products in healthcare that can put workers and patients under regular and intense exposure to BPA.
Preliminary Opinion on the safety of the use of bisphenol A in medical devices

Fields marked with * are mandatory.

Personal information

Last Name
Amaral

First name
Maria José

Organisation/company
HCWH Europe

E-mail
maria.jose@hcwh.org

Country
Afghanistan
Albania
Algeria
American Samoa
Andorra
Angola
Anguilla
Antigua and Barbuda
Argentina
Armenia
Aruba
Australia
Austria
Azerbaijan
Bahamas
Bahrain
Bangladesh
Barbados
Belarus
Belgium
Belize
Benin
Bermuda
Bhutan
Bolivia
Bosnia-Herzegovina
Botswana
Bouvet Island
Brazil
Brunei
Bulgaria
Burkina Faso
Burundi
Cambodia
Cameroon
Canada
Cape Verde
Cayman Islands
Central African Republic
Chad
Chile
China
Christmas Island
Cocos (Keeling) Islands
Colombia
Comoros
Congo, Democratic Republic of the (Zaire)
Congo, Republic of
Cook Islands
Costa Rica
Croatia
Cuba
Cyprus
Czech Republic
Denmark
Djibouti
Dominica
Dominican Republic
Ecuador
Egypt
El Salvador
Equatorial Guinea
Eritrea
Estonia
Ethiopia
Falkland Islands
Faroe Islands
Fiji
Finland
France
French Guiana
Gabon
Gambia
Georgia
Germany
Ghana
Gibraltar
Greece
Greenland
Grenada
Guadeloupe (French)
Guam (USA)
Guatemala
Guinea
Guinea Bissau
Guyana
Haiti
Holy See
Honduras
Hong Kong
Hungary
Iceland
India
Indonesia
Iran
Iraq
Ireland
Israel
Italy
Ivory Coast (Côte D’Ivoire)
Jamaica
Japan
Jordan
Kazakhstan
Kenya
Kiribati
Kuwait
Kyrgyzstan
Laos
Latvia
Lebanon
Lesotho
Liberia
Libya
Liechtenstein
Lithuania
Luxembourg
Macau
Macedonia
Madagascar
Malawi
Malaysia
Maldives
Mali
Malta
Marshall Islands
Martinique (French)
Mauritania
Mauritius
Mayotte
Mexico
Micronesia
Moldova
Monaco
Mongolia
Montenegro
Montserrat
Morocco
- Mozambique
- Myanmar
- Namibia
- Nauru
- Nepal
- Netherlands
- Netherlands Antilles
- New Caledonia (French)
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- North Korea
- Northern Mariana Islands
- Norway
- Oman
- Pakistan
- Palau
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Island
- Poland
- Polynesia (French)
- Portugal
- Puerto Rico
- Qatar
- Reunion
- Romania
- Russia
- Rwanda
- Saint Helena
- Saint Kitts and Nevis
- Saint Lucia
- Saint Pierre and Miquelon
- Saint Vincent and Grenadines
- Samoa
- San Marino
- Sao Tome and Principe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen Islands
- Swaziland
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- Timor-Leste (East Timor)
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
Chapter/section

If you have comments on different chapters/sections, please select the chapter, add your comment, and submit your comments separately. Please also upload the scientific papers you consider relevant for that section/chapter. Repeat this operation for each chapter you would like to comment on. After sending a comment, it will be indicated if it has been sent successfully and you will be able to enter your next comment.

Table of content

1. BACKGROUND
2. TERMS OF REFERENCE
3. SCIENTIFIC RATIONALE
   3.1. Introduction
   3.2. Methodology
   3.3. Chemistry of BPA
   3.4. Physico-Chemical Properties
   3.5. Overview of existing assessments on BPA
      3.5.1. Existing assessments
      3.5.2. Controversial issues
      3.5.3. Conclusion
   3.6. Identification of the relevant medical devices
      3.6.1. Medical devices
      3.6.2. Presence in and release of BPA from medical devices
      3.6.3. Conclusions
   3.7. Exposure scenarios
      3.7.1. Knowledge on BPA exposure
         3.7.1.1. Methods for measurement of internal exposure in humans
         3.7.1.2. Internal exposure to BPA in humans from all routes
3.7.3. Exposure to BPA from medical devices under different scenarios
3.7.4. BPA exposure from uses of BPA containing PVC
3.7.5. Conclusions
3.8. Toxicokinetics of bisphenol A
3.8.1. BPA biotransformation
3.8.2. Toxicokinetics after oral uptake
3.8.3. Toxicokinetics after uptake by other routes
3.8.3.1. Toxicokinetics after dermal and transcutaneous uptake
3.8.3.2. Toxicokinetics after intravenous administration
3.8.3.3. Toxicokinetics after inhalation
3.8.4. Special considerations on susceptible populations
3.8.5. Conclusions
3.9. Toxicity
3.9.1. General toxicity studies
3.9.1.1. Acute toxicity
3.9.1.2. Chronic toxicity (repeated-dose) studies
3.9.2. Genotoxicity
3.9.3. Carcinogenicity
3.9.4. Neurotoxicity and behavioural toxicity
3.9.5. Immunotoxicity
3.9.6. Cardiovascular effects
3.9.7. Metabolic disorders
3.9.8. Reproductive and developmental toxicity
3.9.9. Conclusions on toxicity
3.10. Epidemiological studies
3.11. Alternatives to BPA currently use
3.12. Recommendations for research

4. OPINION
5. MINORITY OPINION
6. LIST OF ABBREVIATIONS
7. REFERENCES
8. ANNEXES
The presence of BPA in PVC medical devices is not well addressed in the opinion. One one side, the opinion is relying exclusively in information provided by the industry, that BPA is not longer used in the production of PVC by European PVC manufacturers. This information should be verified by an independent regulatory body. For example, in the case of CMR phthalates in toys, that are regulated by EU law, the Swedish chemicals regulatory agency found several products in the market that did not comply with the law. On the other side, even accepting the claim as correct for the European PVC manufacturers, this means very little on the global medical device market. The opinion neglects that both medical devices manufacturers and medical devices procurers have suppliers outside of the European market, where PVC containing BPA can still be the norm. For example, 10 million surgical interments used each year by NHS UK are manufactured in Pakistan. Furthermore, many of the main European manufacturers of medical devices admit they cannot enquire their manufacturers if a certain chemical has been added or not (for further information see Green Public Procurement criteria for BPA in medical devices). The issue of PVC medical devices containing BPA is of high concern, as most of these medical devices are used to provide intravenously solutions to patients, where the problem of migration of the plastic material and leaching is greatest. Finally, BPA is also used in the production of polyacrylates used in coating of medical devices, and in polyetherimide plastics like sterilisation trays and dentist devices.