



# SECTION OF EVIDENCE SYNTHESIS AND CLASSIFICATION (ESC)

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### Group head

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Dr Kurt Straif (until April 2019)

## WHO Classification of Tumours Group (WCT)

### Group head

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## Student

Ms Katherine Lloyd  
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The Section of Evidence Synthesis and Classification (ESC), headed by Dr Ian Cree, comprises three Groups: the IARC Monographs Group (IMO), the IARC Handbooks Group (IHB), and the WHO Classification of Tumours Group (WCT).

The IARC Monographs Group (IMO), headed (acting) by Dr Mary Schubauer-Berigan, produces the *IARC Monographs on the Identification of Carcinogenic Hazards to Humans*, a series of systematic scientific reviews that identify environmental factors that may cause cancer in humans. IMO also organizes Advisory Groups and international scientific workshops on key

issues pertaining to the assessment of carcinogens and their mechanisms.

The IARC Handbooks Group (IHB), headed by Dr Béatrice Lauby-Secretan, produces the *IARC Handbooks of Cancer Prevention*. This series of systematic scientific reviews identifies interventions and strategies that can reduce the risk of cancer or mortality from cancer.

The WHO Classification of Tumours Group (WCT), headed by Dr Ian Cree, produces the *WHO Classification of Tumours* series (also known as the WHO Blue Books). Now in its fifth edition as a series of 15 volumes, it provides the

definitive and internationally accepted standards for the diagnosis of tumours.

For each volume of the *IARC Monographs*, the *IARC Handbooks*, and the *WHO Classification of Tumours*, IARC convenes international, interdisciplinary groups of expert scientists and physicians to systematically review the pertinent scientific literature and develop consensus evaluations and classifications. IARC selects these experts on the basis of their knowledge and experience as well as an absence of conflicting interests.

## IARC MONOGRAPHS GROUP (IMO)

The IARC Monographs Group (IMO) is responsible for producing the *IARC Monographs on the Identification of Carcinogenic Hazards to Humans*. The *IARC Monographs* are fundamental to the Agency's mission of identifying the preventable causes of human cancer. Since the inception of the *Monographs* programme in 1971, more than 1000 agents have been evaluated

for carcinogenicity. This international, interdisciplinary endeavour provides an authoritative reference for researchers, health authorities, and the public. Health agencies worldwide rely on the *Monographs* for the scientific support of actions to control exposures and prevent cancer. In addition to producing this important resource, the scientific personnel of IMO contribute to the

scientific literature on topics related to the methodology and contents of the *Monographs*.

### MAJOR ACCOMPLISHMENTS

IMO organized five Working Group meetings during the 2018–2019 biennium (Figure 1). The agents evaluated at the five Working Group meetings included

Figure 1. The Working Group meeting for IARC Monographs Volume 124, held in June 2019. © IARC.



**Table 1. Summary of evaluations from the five *Monographs* meetings held in 2018–2019**

Agent (Volume)	Evaluation <sup>a</sup>	Strength of evidence of cancer in humans (tumour type provided for <i>limited evidence</i> )	Strength of evidence of carcinogenicity in experimental animals	Key characteristics of carcinogens with strong evidence <sup>b</sup>
<i>Styrene, Styrene-7,8-Oxide, and Quinoline (Volume 121)</i>				
Styrene	Group 2A	<i>Limited</i> (lymphohaematopoietic malignancies)	<i>Sufficient</i>	Multiple (1, 2, 8, 10)
Styrene-7,8-oxide	Group 2A	<i>Inadequate</i>	<i>Sufficient</i>	Multiple (1, 2, 10)
Quinoline	Group 2B	<i>Inadequate</i>	<i>Sufficient</i>	2
<i>Isobutyl Nitrite, β-Picoline, and Some Acrylates (Volume 122)</i>				
Isobutyl nitrite	Group 2B	<i>Inadequate</i>	<i>Sufficient</i>	None
β-Picoline	Group 3	<i>Inadequate</i>	<i>Limited</i>	None
Methyl acrylate	Group 2B	<i>Inadequate</i>	<i>Sufficient</i>	None
Ethyl acrylate	Group 2B	<i>Inadequate</i>	<i>Sufficient</i>	Multiple (6, 10)
2-Ethylhexyl acrylate	Group 2B	<i>Inadequate</i>	<i>Sufficient</i>	None
Trimethylolpropane triacrylate	Group 2B	<i>Inadequate</i>	<i>Sufficient</i>	None
<i>Some Nitrobenzenes and Other Industrial Chemicals (Volume 123)</i>				
2-Chloronitrobenzene	Group 2B	<i>Inadequate</i>	<i>Sufficient</i>	None
4-Chloronitrobenzene	Group 2B	<i>Inadequate</i>	<i>Sufficient</i>	None
1,4-Dichloro-2-nitrobenzene	Group 2B	<i>Inadequate</i>	<i>Sufficient</i>	None
2,4-Dichloro-1-nitrobenzene	Group 2B	<i>Inadequate</i>	<i>Sufficient</i>	None
2-Amino-4-chlorophenol	Group 2B	<i>Inadequate</i>	<i>Sufficient</i>	None
<i>ortho</i> -Phenylenediamine and <i>ortho</i> -phenylenediamine dihydrochloride	Group 2B	<i>Inadequate</i>	<i>Sufficient</i>	2
<i>para</i> -Nitroanisole	Group 2B	<i>Inadequate</i>	<i>Sufficient</i>	None
<i>N,N</i> -Dimethylacetamide	Group 2B	<i>Inadequate</i>	<i>Sufficient</i>	None
<i>Night Shift Work (Volume 124)</i>				
Night shift work	Group 2A	<i>Limited</i> (breast, colorectum, prostate)	<i>Sufficient</i>	Multiple (6, 7, 10)
<i>Some Industrial Chemical Intermediates and Solvents (Volume 125)</i>				
Allyl chloride	Group 3	<i>Inadequate</i>	<i>Limited</i>	None
1-Bromo-3-chloropropane	Group 2B	<i>Inadequate</i>	<i>Sufficient</i>	10
1-Butyl glycidyl ether	Group 2B	<i>Inadequate</i>	<i>Sufficient</i>	10
4-Chlorobenzotrifluoride	Group 2B	<i>Inadequate</i>	<i>Sufficient</i>	None
Glycidyl methacrylate	Group 2A	<i>Inadequate</i>	<i>Sufficient</i>	Multiple (2 <sup>c</sup> , 10) <sup>d</sup>

<sup>a</sup> Group 2A, probably carcinogenic to humans; Group 2B, possibly carcinogenic to humans; Group 3, not classifiable as to its carcinogenicity to humans.

<sup>b</sup> Numbers correspond to one or more of the 10 key characteristics of carcinogens, as identified by Smith et al. (2016; <https://www.ncbi.nlm.nih.gov/pubmed/?term=26600562>) and described in the Preamble to the *IARC Monographs* (<https://monographs.iarc.fr/preamble-to-the-iarc-monographs/>).

<sup>c</sup> In human primary cells.

<sup>d</sup> There is also strong evidence that glycidyl methacrylate belongs, based on mechanistic considerations, to a class of reactive agents (glycidyl epoxides) for which one member has been classified as probably carcinogenic to humans.

several that had been recommended as priorities for evaluation:

- Volume 121: Styrene, Styrene-7,8-Oxide, and Quinoline (20–27 March 2018)
- Volume 122: Isobutyl Nitrite, β-Picoline, and Some Acrylates (5–12 June 2018)
- Volume 123: Some Nitrobenzenes and Other Industrial Chemicals (9–16 October 2018)
- Volume 124: Night Shift Work (4–11 June 2019)
- Volume 125: Some Industrial Chemical Intermediates and Solvents (5–11 November 2019).

Table 1 presents the results of these meetings, highlighting the important

contribution of the *Monographs* in evaluating the carcinogenicity of diverse agents. These agents range from chemicals tested only in animal bioassays to complex exposures that have been evaluated in epidemiological and mechanistic studies, such as night shift work.

The evaluations reached in these meetings included 24 classifications, comprising 14 agents never before evaluated by IARC and re-evaluations of 10 agents considered previously.

A concise summary of each evaluation with the classification, accompanying rationale, and key references is published

in *The Lancet Oncology* within several weeks of each meeting. Full details and supporting data are provided in the complete *Monograph*, which is expected to be published about a year after a meeting. Both are available for free download from the *Monographs* website (<https://monographs.iarc.fr/monographs-available/>).

IMO also convened two Advisory Group meetings during the biennium:

- Advisory Group to Recommend an Update to the Preamble to the *IARC Monographs* (12–14 November 2018)
- Advisory Group to Recommend Priorities for the *IARC Monographs* during 2020–2024 (25–27 March 2019).

The Advisory Group to Recommend an Update to the Preamble to the *IARC Monographs* comprised 21 experts from nine countries. Two invited specialists, seven representatives of national and international health agencies, three observers from interested organizations, and 16 members of the IARC/WHO secretariat also attended the meeting. This revision of the Preamble was a critical milestone for IARC, updating the rigorous criteria and procedures for the scientific review and evaluation of carcinogenic hazards by independent experts, free from vested interests (see <https://monographs.iarc.fr/wp-content/uploads/2019/01/Preamble-2019.pdf>). An article describing the rationale for and new features of the revised Preamble was published in the *Journal of the National Cancer Institute*.

The Advisory Group to Recommend Priorities for the *IARC Monographs* during

2020–2024 comprised 29 scientists from 18 countries. The Advisory Group assessed the response to a public call for nominations and considered more than 170 unique candidate agents. A broad range of agents were recommended with high, medium, or low priority for evaluation, on the basis of evidence of human exposure and the extent of available evidence for evaluating carcinogenicity (see [https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(19\)30246-3/fulltext](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(19)30246-3/fulltext) and Tables 2 and 3). These recommendations will help to ensure that the *IARC Monographs* evaluations reflect the current state of scientific evidence relevant to carcinogenicity.

#### PUBLICATIONS

During the 2018–2019 biennium, the following *IARC Monographs* Volumes were published:

- Volume 122: Isobutyl Nitrite,  $\beta$ -Picoline, and Some Acrylates (2019)

- Volume 121: Styrene, Styrene-7,8-oxide, and Quinoline (2019)
- Volume 120: Benzene (2018)
- Volume 119: Some Chemicals That Cause Tumours of the Urinary Tract in Rodents (2019)
- Volume 118: Welding, Molybdenum Trioxide, and Indium Tin Oxide (2018)
- Volume 117: Pentachlorophenol and Some Related Compounds (2019)
- Volume 116: Drinking Coffee, Mate, and Very Hot Beverages (2018)
- Volume 115: Some Industrial Chemicals (2018)
- Volume 114: Red Meat and Processed Meat (2018)
- Volume 113: DDT, Lindane, and 2,4-D (2018).

IARC Scientific Publication No. 165 (Tumour Site Concordance and Mechanisms of Carcinogenesis) was also published during the biennium.

**Table 2. Agents recommended for evaluation by *IARC Monographs* during 2020–2024 with high priority<sup>a</sup>**

Agent name	Rationale
<i>Agents not previously evaluated by IARC Monographs</i>	
Haloacetic acids (and other disinfection by-products)	Relevant human cancer, bioassay, and mechanistic evidence
Metalworking fluids	Relevant human cancer and bioassay evidence
Cannabis smoking, fertility treatment, glucocorticoids, <i>Salmonella typhi</i> , sedentary behaviour <sup>b</sup> , tetracyclines and other photosensitizing drugs	Relevant human cancer and mechanistic evidence
Cupferron, gasoline oxygenated additives, gentian violet, glycidamide, malachite green and leucomalachite green, oxymetholone, pentabromodiphenyl ethers, vinclozolin	Relevant bioassay and mechanistic evidence
Breast implants, dietary salt intake <sup>b</sup> , neonatal phototherapy <sup>b</sup> , poor oral hygiene <sup>b</sup>	Relevant human cancer evidence
Aspartame	Relevant bioassay evidence
Arecoline, carbon disulfide, electronic nicotine delivery systems and nicotine <sup>b</sup> , human cytomegalovirus, parabens	Relevant mechanistic evidence
<i>Agents previously evaluated by IARC Monographs<sup>c</sup></i>	
Automotive gasoline (leaded and unleaded), carbaryl, malaria	New human cancer, bioassay, and mechanistic evidence to warrant re-evaluation of the classification
Acrylamide <sup>b</sup> , acrylonitrile, some anthracyclines, coal dust, combustion of biomass, domestic talc products, firefighting exposure, metallic nickel, some pyrethroids (i.e. permethrin, cypermethrin, deltamethrin)	New human cancer and mechanistic evidence to warrant re-evaluation of the classification
Aniline, acrolein, methyl eugenol and isoeugenol <sup>b</sup> , multiwalled carbon nanotubes <sup>b</sup> , non-ionizing radiation (radiofrequency) <sup>b</sup> , some perfluorinated compounds (e.g. perfluorooctanoic acid)	New bioassay and mechanistic evidence to warrant re-evaluation of the classification
Estrogen:estradiol and estrogen–progestogens <sup>d</sup> , hydrochlorothiazide, Merkel cell polyomavirus, perchloroethylene, very hot foods and beverages	New human cancer evidence to warrant re-evaluation of the classification
1,1,1-Trichloroethane, weapons-grade tungsten/nickel/cobalt alloy	New bioassay evidence to warrant re-evaluation of the classification
Acetaldehyde, bisphenol A <sup>b</sup> , cobalt and cobalt compounds, crotonaldehyde, cyclopeptide cyanotoxins, fumonisin B <sub>1</sub> , inorganic lead compounds, isoprene, o-anisidine	New mechanistic evidence to warrant re-evaluation of the classification

<sup>a</sup> Evidence of human exposure was identified for all agents.

<sup>b</sup> Advisory Group recommend an evaluation in the latter half of the 5-year period.

<sup>c</sup> See <https://monographs.iarc.fr/list-of-classifications-volumes/> for list of current classifications.

<sup>d</sup> Group 1 carcinogen; new evidence of cancer in humans indicates possible causal association(s) for additional tumour site(s) (see Section 3 of Preamble to the *IARC Monographs*, <https://monographs.iarc.fr/preamble-to-the-iarc-monographs/>).

**Table 3. Agents recommended for evaluation by IARC Monographs during 2020–2024 with medium and low priority<sup>a</sup>**

Agent name	Previous evaluation status
<i>Medium-priority agents</i>	
2,3-Butanedione (diacetyl), alachlor, biphenyl, chlorinated paraffins, chlorpyrifos, C.I. Direct Blue 218, diphenylamine, hydrazobenzene, indole-3-carbinol, mancozeb, nanomaterials (e.g. titanium dioxide or nanosilica), nitrogen dioxide, <i>o</i> -benzyl- <i>p</i> -chlorophenol, ozone, pendimethalin, sleep, styrene-acrylonitrile trimer, terbufos, tris(chloropropyl)phosphate	Agents not previously evaluated by IARC Monographs
Aflatoxins <sup>b</sup> , anthracene, antimony trioxide, atrazine, bromate compounds, dimethyl hydrogen phosphite, furan, <i>N</i> -methylolacrylamide, <i>p</i> -nitrotoluene, <i>Schistosoma mansoni</i> , tris(2-chloroethyl) phosphate, tobacco smoking (including second-hand) <sup>b</sup>	Agents previously evaluated by IARC Monographs <sup>c</sup>
<i>Low-priority agents</i>	
2-Hydroxy-4-methoxybenzophenone, aluminium, androstenedione, butyl methacrylate, cinidon ethyl, dysbiotic microbiota, fonofos, furmecycloz, isoflavones, isophorone, laboratory work and occupation as a chemist, methanol, <i>S</i> -ethyl- <i>N,N</i> -dipropylthiocarbamate, semiconductor manufacturing, sucralose	Agents not previously evaluated by IARC Monographs
1,1-Dimethylhydrazine, benzophenone-1, carbon black, catechol, chlordecone, cumene, dichloromethane, hepatitis D virus, human papillomavirus (beta (cutaneous) and some alpha (mucosal) types), <i>Opisthorchis felineus</i> , outdoor air pollution <sup>b</sup> , pyrrolizidine alkaloids, selenium and selenium compounds	Agents previously evaluated by IARC Monographs <sup>c</sup>

<sup>a</sup> Evidence of human exposure was identified for all agents.

<sup>b</sup> Group 1 carcinogen; new evidence of cancer in humans indicates possible causal association(s) for additional tumour site(s) (see Section 3 of Preamble to the IARC Monographs, <https://monographs.iarc.fr/preamble-to-the-iarc-monographs/>).

<sup>c</sup> See <https://monographs.iarc.fr/list-of-classifications-volumes/> for list of current classifications.

## IARC HANDBOOKS GROUP (IHB)

The IARC Handbooks Group (IHB) is responsible for producing the IARC *Handbooks of Cancer Prevention*. The objective of the IARC *Handbooks* is to publish critical reviews and evaluations of interventions and strategies that can reduce the burden of cancer. The principles of systematic review are applied to the identification, screening, synthesis, and evaluation of the evidence. Interventions or strategies are selected for evaluation on the basis of published scientific evidence of preventive effects and potential public health relevance. *Handbooks* evaluations have included

chemopreventive agents, preventive actions, effectiveness of screening, and effectiveness of tobacco control. The *Handbooks* are used worldwide by public health representatives to set guidelines and recommendations for cancer prevention.

### MAJOR ACCOMPLISHMENTS

IHB organized three meetings during the biennium: the Working Group meeting for IARC *Handbooks* Volume 17 (Colorectal Cancer Screening), an Advisory Group meeting to Recommend an Update to

the Preambles to the IARC *Handbooks* (previous referred to as the IARC *Handbooks* Working Procedures), and a scoping meeting for IARC *Handbooks* Volume 18 (Cervical Cancer Screening).

### VOLUME 17: COLORECTAL CANCER SCREENING (14–21 NOVEMBER 2017)

The outcome of the meeting was published in *The New England Journal of Medicine* in March 2018 (Table 4). The full report is available for free download in PDF format from the IARC Publications website (<http://publications.iarc.fr/573>).

**Table 4. IARC Handbooks Volume 17: Summary of the evaluations of the different colorectal cancer screening techniques**

Screening technique	Strength of evidence		
	Reduction in CRC incidence	Reduction in CRC mortality	Benefit–harm ratio
Biennial screening with gFOBT without rehydration	<i>Evidence suggesting lack of effect</i>	<i>Sufficient</i>	<i>Sufficient</i>
Annual or biennial screening with gFOBT of higher sensitivity	<i>Limited</i>	<i>Sufficient</i>	<i>Sufficient</i>
Biennial screening with FIT	<i>Limited</i>	<i>Sufficient</i>	<i>Sufficient</i>
Single screening with sigmoidoscopy	<i>Sufficient</i>	<i>Sufficient</i>	<i>Sufficient</i>
Single screening with colonoscopy	<i>Sufficient</i>	<i>Sufficient</i>	<i>Sufficient</i>
Single screening with CTC	<i>Limited</i>	<i>Limited</i>	<i>Inadequate</i>

CRC, colorectal cancer; CTC, computed tomography colonography; FIT, faecal immunochemical test; gFOBT, guaiac faecal occult blood test.

## UPDATE TO THE PREAMBLES (11–13 FEBRUARY 2019)

IARC convened an Advisory Group to Recommend an Update to the Preambles to the *IARC Handbooks* (previously referred to as the *IARC Handbooks Working Procedures*), to reflect on the scientific developments and procedural changes that have occurred in the fields of primary and secondary prevention. This was the first update of the procedures by an external Advisory Group since the launch of the *Handbooks* programme, in 1995, and represents a major milestone in the development of the programme. The Advisory Group made recommendations on several overarching issues, including the scope of the programme, future priorities, transparency of the systematic review process, and evaluation schemes. The Advisory Group also recommended that IARC continue to develop approaches to disseminate the findings of the *Handbooks*.

An internal Advisory Group Report explains the process followed and highlights the main updates. The Instructions for Authors, which constitute the documentation used for implementing the principles laid out in the Preambles, have been revised in line with the updated Preambles.

All documents listed are available on the *Handbooks* website (<http://handbooks.iarc.fr/>).

### VOLUME 18: CERVICAL CANCER SCREENING (SCOPING MEETING, 14–16 OCTOBER 2019)

Cervical cancer screening will be re-evaluated at a meeting on 23–30 June 2020, at which new screening technologies, including human papillomavirus (HPV) testing, and the implementation of screening in the context of HPV vaccination will be considered. This *Handbook* is an integral part of the WHO Global Cervical

Cancer Elimination Initiative, launched following the call by Dr Tedros Adhanom Ghebreyesus at the World Health Assembly in May 2018. This will be the first close collaboration between the *Handbooks* programme and WHO, and will allow the *Handbooks* evaluations to be considered during the WHO process to develop recommendations.

### PUBLICATIONS

- Volume 16 of the *IARC Handbooks*, Absence of Excess Body Fatness, was published online in October 2018 and in print in July 2019.
- Volume 17 of the *IARC Handbooks*, Colorectal Cancer Screening, was published online in June 2019 and in print in October 2019.

## WHO CLASSIFICATION OF TUMOURS GROUP (WCT)

The WHO Classification of Tumours Group (WCT) was established in 2017 and took over the publication of the WHO Classification of Tumours series (also known as the WHO Blue Books). Previously published in its 12-volume fourth edition, the series was revised for its 15-volume fifth edition to encompass the formation of a formal *WHO Classification of Tumours* Editorial Board to advise IARC on content (Figure 2). The WHO Blue Books are of considerable importance in both cancer diagnosis and research, and provide the international criteria and standards against which tumours are diagnosed. The definitive diagnosis and classification of individual cancers in turn underpins research into cancer causation, prevention, diagnosis, and treatment.

During the 2018–2019 biennium, the following volumes were published:

- *WHO Classification of Skin Tumours*, fourth edition (2018)
- *WHO Classification of Tumours of the Eye*, fourth edition (2018)
- *Digestive System Tumours*, fifth edition (2019)
- *Breast Tumours*, fifth edition (2019).

Pathology is currently undergoing a more rapid transformation than at any time during the past 30 years, as a result of the introduction of new technologies. Whereas cancer classification has previously been based on consensus of histopathological opinion, the understanding of cancer at a molecular level is now at a point where it needs to be integrated into diagnosis. In addition, digital pathology and image analysis are producing new insights and providing quantitative justification of many existing diagnostic criteria, while challenging others. Finally, the pace of

improvement in computer technology, including artificial intelligence, is already producing clinically applicable aids to diagnosis, and this trend is likely to accelerate. There is an urgent need to integrate these facets of diagnosis into cancer classification.

WCT provides a timely, definitive synthesis for tumour classification based on an expert consensus review of reproducible peer-reviewed published evidence. Dr Iciar Indave, appointed as systematic reviewer, ensures that the methods used by WCT to assess evidence are as robust as possible given the volume of information available and the timescale for updates.

The WHO Blue Books are available in multiple formats to meet the needs of users in low-, middle-, and high-income countries. The new website, launched

Figure 2. The first meeting of the WHO Classification of Tumours Editorial Board. © IARC.



in September 2019, provides a platform from which additional content can be added to the volumes, including whole slide images of histopathology and clinical images including radiology. WCT works in collaboration with other organizations to advance the practice of high-quality cancer pathology diagnostic practice

and research globally. The WHO Blue Books provide an invaluable resource for both trainee junior pathologists and experienced pathologists.

Finally, WCT collaborates with other researchers, particularly in computational pathology, molecular pathology, and

evidence-based pathology evaluations (systematic reviews). WCT hosts the histology laboratory, run by a laboratory scientist and supervised by highly experienced pathologists, providing a centralized service for histopathology to IARC.