

疫学研究で得られた用量反応データへのBMD法の適用に関する 調査報告書

別添：収集した資料のリスト

- ①収集した論文リスト（324件）
- ②論文リスト：全文入手区分1（16件）
- ③海外評価機関等が作成した評価書等の引用文献（27件）
- ④海外評価機関等が作成した評価書等（46件）

収集した論文リスト (324件)

資料 No.	報告書表4 全文の確認 結果をもとに 本調査の対 象とした文献 一覧のNo.	報告書表8 海外評価機 関等が作成し た評価書等 の引用文献 一覧のNo.	重要資料番 号 (報告書 表10重要資 料の一覧の No.)	著者	タイトル	DOI	書誌情報	発行年	資料のテーマ (内容) 01 : 疫学データにBMD法を 適用する際の考え方・手順の 整理 02 : 疫学データへのBMD法 の適用 03 : 01及び02の両方 04 : その他	文献の種類 01 : 原著 02 : 総説 03 : その他
1				Birgisdottir, B E; Knutsen, H K; Haugen, M; Gjelstad, I M; Jenssen, M T S; Ellingsen, D G; Thomassen, Y; Alexander, J; Meltzer, H M; Brantsæ ter, A L	Essential and toxic element concentrations in blood and urine and their associations with diet: results from a Norwegian population study including high-consumers of seafood and game	10.1016/j.scitotenv. 2013.06.078	The Science of the total environment. 2013, 463- 464, 836-44	2013	04 : その他	01 : 原著
2				Fotland, T Ø; Paulsen, J E; Sanner, T; Alexander, J; Husøy, T	Risk assessment of coumarin using the bench mark dose (BMD) approach: children in Norway which regularly eat oatmeal porridge with cinnamon may exceed the TDI for coumarin with several folds	10.1016/j.fct.2011.1 2.005	Food and chemical toxicology : an international journal published for the British Industrial Biological Research Association. 2012, 50(3-4)903-12	2012	04 : その他	01 : 原著
3	1		51	Jensen, Signe M; Kluxen, Felix M; Ritz, Christian	A Review of Recent Advances in Benchmark Dose Methodology	10.1111/risa.13324	Risk analysis : an official publication of the Society for Risk Analysis. 2019, 39(10)2295-2315	2019	01 : 疫学データに BMD法を適用する際 の考え方・手順の整理	02 : 総説
4	2		12	Noble, Robert B; Bailer, A John; Park, Robert	Model-averaged benchmark concentration estimates for continuous response data arising from epidemiological studies	10.1111/j.1539- 6924.2008.01178.x	Risk analysis : an official publication of the Society for Risk Analysis. 2009, 29(4)558-64	2009	03 : 01及び02の両 方	01 : 原著
5	3		52	Kullar, Savroop S; Shao, Kan; Surette, Céline; Foucher, Delphine; Mergler, Donna; Cormier, Pierre; Bellinger, David C; Barbeau, Benoit; Sauvé, Sébastien; Bouchard, Maryse F	A benchmark concentration analysis for manganese in drinking water and IQ deficits in children	10.1016/j.envint.20 19.05.083	Environment international. 2019, 130, 104889	2019	02 : 疫学データへの BMD法の適用	01 : 原著
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7	4			Murata, Katsuyuki; Budtz-Jørgensen, Esben; Grandjean, Philippe	Benchmark dose calculations for methylmercury-associated delays on evoked potential latencies in two cohorts of children	10.1111/0272- 4332.00034	Risk analysis : an official publication of the Society for Risk Analysis. 2002, 22(3)465-74	2002	02 : 疫学データへの BMD法の適用	01 : 原著
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12				Wignall, Jessica A; Shapiro, Andrew J; Wright, Fred A; Woodruff, Tracey J; Chiu, Weihsueh A; Guyton, Kathryn Z; Rusyn, Ivan	Standardizing benchmark dose calculations to improve science-based decisions in human health assessments	10.1289/ehp.13075 39	Environmental health perspectives. 2014, 122(5)499-505	2014	01 : 疫学データに BMD法を適用する際 の考え方・手順の整理	01 : 原著

13	5	29		van Wijngaarden, Edwin; Beck, Christopher; Shamlaye, Conrad F; Cernichiari, Elsa; Davidson, Philip W; Myers, Gary J; Clarkson, Thomas W	Benchmark concentrations for methyl mercury obtained from the 9-year follow-up of the Seychelles Child Development Study	10.1016/j.neuro.2006.05.016	Neurotoxicology. 2006, 27(5)702-9	2006	02 : 疫学データへのBMD法の適用	01 : 原著
14	6	31		Kobayashi, Etsuko; Suwazono, Yasushi; Dochi, Mirei; Honda, Ryumon; Nishijo, Muneko; Kido, Teruhiko; Nakagawa, Hideaki	Estimation of benchmark doses as threshold levels of urinary cadmium, based on excretion of beta2-microglobulin in cadmium-polluted and non-polluted regions in Japan	10.1016/j.toxlet.2008.04.013	Toxicology letters. 2008, 179(2)108-12	2008	02 : 疫学データへのBMD法の適用	01 : 原著
15	7			Suwazono, Yasushi; Sakata, Kouichi; Harada, Hideto; Oishi, Mitsuhiro; Okubo, Yasushi; Uetani, Mirei; Kobayashi, Etsuko; Nogawa, Koji	Benchmark dose of working hours in relation to subjective fatigue symptoms in Japanese male workers	10.1016/j.annepidem.2006.01.003	Annals of epidemiology. 2006, 16(9)726-32	2006	02 : 疫学データへのBMD法の適用	01 : 原著
17	8	10		Budtz-Jorgensen, E; Grandjean, P; Keiding, N; White, R F; Weihe, P	Benchmark dose calculations of methylmercury-associated neurobehavioural deficits	10.1016/S0378-4274(99)00283-0	Toxicology letters. 2000, 112-113,193-9	2000	02 : 疫学データへのBMD法の適用	01 : 原著
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21				Deutsch, Roland C; Piegorsch, Walter W	Benchmark dose profiles for joint-action quantal data in quantitative risk assessment	10.1111/j.1541-0420.2012.01811.x	Biometrics. 2012, 68(4)1313-22	2012	01 : 疫学データにBMD法を適用する際の考え方・手順の整理	01 : 原著
22		8		Gaylor, D W; Kodell, R L; Chen, J J; Krewski, D	A unified approach to risk assessment for cancer and noncancer endpoints based on benchmark doses and uncertainty/safety factors	10.1006/rtp.1998.1279	Regulatory toxicology and pharmacology : RTP. 1999, 29(2 Pt 1)151-7	1999	01 : 疫学データにBMD法を適用する際の考え方・手順の整理	02 : 総説
23	11	48	14	Budtz-Jørgensen, Esben; Keiding, Niels; Grandjean, Philippe	Effects of exposure imprecision on estimation of the benchmark dose	10.1111/j.0272-4332.2004.00560.x	Risk analysis : an official publication of the Society for Risk Analysis. 2004, 24(6)1689-96	2004	03 : 01及び02の両方	01 : 原著
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25	13			Rabovsky, J; Fowles, J; Hill, M D; Lewis, D C	A health risk benchmark for the neurologic effects of styrene: comparison with NOAEL/LOAEL approach	10.1111/0272-4332.211095	Risk analysis : an official publication of the Society for Risk Analysis. 2001, 21(1)117-26	2001	02 : 疫学データへのBMD法の適用	01 : 原著
27	14			Hong, Feng; Jin, Tai-yi; Zhang, Ai-hua	Calculation of the combined renal dysfunction risk in patients co-exposed to arsenicum and cadmium by using benchmark dose method	なし	Zhonghua yu fang yi xue za zhi [Chinese journal of preventive medicine]. 2004, 38(6)374-8	2004	02 : 疫学データへのBMD法の適用	01 : 原著

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30	15	43		Grandjean, Philippe; Budtz-Jørgensen, Esben	Immunotoxicity of perfluorinated alkylates: calculation of benchmark doses based on serum concentrations in children	10.1186/1476-069X-12-35	Environmental health : a global access science source. 2013, 12(1)35	2013	02 : 疫学データへのBMD法の適用	02 : 総説
32	16	28		Suwazono, Yasushi; Sand, Salomon; Vahter, Marie; Filipsson, Agneta Falk; Skerfving, Staffan; Lidfeldt, Jonas; Akesson, Agneta	Benchmark dose for cadmium-induced renal effects in humans	10.1289/ehp.9028	Environmental health perspectives. 2006, 114(7)1072-6	2006	02 : 疫学データへのBMD法の適用	01 : 原著
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37	20	40		Suwazono, Yasushi; Nogawa, Kazuhiro; Uetani, Mirei; Nakada, Satoru; Kido, Teruhiko; Nakagawa, Hideaki	Application of the hybrid approach to the benchmark dose of urinary cadmium as the reference level for renal effects in cadmium polluted and non-polluted areas in Japan	10.1016/j.envres.2010.11.013	Environmental research. 2011, 111(2)312-4	2011	02 : 疫学データへのBMD法の適用	01 : 原著
38	21		53	Kubo, Keiko; Nogawa, Kazuhiro; Kido, Teruhiko; Nishijo, Muneko; Nakagawa, Hideaki; Suwazono, Yasushi	Estimation of Benchmark Dose of Lifetime Cadmium Intake for Adverse Renal Effects Using Hybrid Approach in Inhabitants of an Environmentally Exposed River Basin in Japan	10.1111/risa.12750	Risk analysis : an official publication of the Society for Risk Analysis. 2017, 37(1)20-26	2017	02 : 疫学データへのBMD法の適用	01 : 原著
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42	22			Yan, Jiuming; Huo, Jiao; Li, Renjia; Jia, Zhenchao; Song, Yang; Chen, Jinyao; Zhang, Lishi	Benchmark dose estimation of urinary and blood cadmium as biomarkers of renal dysfunction among 40-75-year-old non-smoking women in rural areas of southwest China	10.1002/jat.3829	Journal of applied toxicology : JAT. 2019, 39(10)1433-1443	2019	02 : 疫学データへのBMD法の適用	01 : 原著
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57	26			Frangos, John; Mikkonen, Antti; Down, Christin	Derivation of an occupational exposure limit for an inhalation analgesic methoxyflurane (Penthrox®)	10.1016/j.yrtph.2016.05.012	Regulatory toxicology and pharmacology : RTP. 2016, 80, 210-25	2016	02 : 疫学データへのBMD法の適用	01 : 原著
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61				Stelljes, Mark E; Wood, Rosemary R	Development of an occupational exposure limit for n-propylbromide using benchmark dose methods	10.1016/j.yrtph.2004.06.006	Regulatory toxicology and pharmacology : RTP. 2004, 40(2)136-50	2004	04 : その他	01 : 原著
63	28			Zou, Kaili; Wang, Pengpeng; Duan, Xiaoran; Yang, Yongli; Zhang, Hui; Wang, Sihua; Shi, Liuhua; Wang, Yanbin; Yao, Wu; Wang, Wei	Benchmark dose estimation for coke oven emissions based on oxidative damage in Chinese exposed workers	10.1016/j.ecoenv.2020.110889	Ecotoxicology and environmental safety. 2020, 202, 110889	2020	02 : 疫学データへのBMD法の適用	01 : 原著
64	29			Sun, Yi; Sun, Donghong; Zhou, Zhijun; Zhu, Guoying; Lei, Lijian; Zhang, Haiying; Chang, Xiuli; Jin, Taiyi	Estimation of benchmark dose for bone damage and renal dysfunction in a Chinese male population occupationally exposed to lead	10.1093/annhyg/mean031	The Annals of occupational hygiene. 2008, 52(6)527-33	2008	02 : 疫学データへのBMD法の適用	01 : 原著
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76	38			Dakeishi, Miwako; Murata, Katsuyuki; Tamura, Akiko; Iwata, Toyoto	Relation between benchmark dose and no-observed-adverse-effect level in clinical research: effects of daily alcohol intake on blood pressure in Japanese salesmen	10.1111/j.1539-6924.2006.00722.	Risk analysis : an official publication of the Society for Risk Analysis. 2006, 26(1)115-23	2006	02 : 疫学データへのBMD法の適用	01 : 原著
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79	41		11	Bi, Jian	Using the benchmark dose (BMD) methodology to determine an appropriate reduction of certain ingredients in food products	10.1111/j.1750-3841.2009.01397.x	Journal of food science. 2010, 75(1)R9-16	2010	03 : 01及び02の両方	01 : 原著
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82	43		55	Chen, Chu-Chih; Wang, Yin-Han; Chen, Wei J; Hsiung, Chao A; Leon Guo, Yue-Liang; Julie Wang, Shu-Li	A benchmark dose study of prenatal exposure to di(2-ethylhexyl) phthalate and behavioral problems in children	10.1016/j.ijheh.2019.06.002	International journal of hygiene and environmental health. 2019, 222(6)971-980	2019	02 : 疫学データへのBMD法の適用	01 : 原著
84	44			Wu, Zhijun; Liu, Qiang; Wang, Chunmin; Xu, Bo; Guan, Mingyue; Ye, Meng; Jiang, Hai; Zheng, Min; Zhang, Man; Zhao, Wenjin; Jiang, Xiao; Leng, Shuguang; Cheng, Juan	A Comparative Benchmark Dose Study for N, N-Dimethylformamide Induced Liver Injury in a Chinese Occupational Cohort	10.1093/toxsci/kfx076	Toxicological sciences : an official journal of the Society of Toxicology. 2017, 158(1)140-150	2017	02 : 疫学データへのBMD法の適用	01 : 原著
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1331				Paustenbach, Dennis J	The U.S. EPA Science Advisory Board Evaluation (2001) of the EPA dioxin reassessment	10.1006/rtph.2002.1580	Regulatory toxicology and pharmacology : RTP. 2002, 36(2)211-9	2002	04 : その他	02 : 総説
1337				Franco, Larissa T; Petta, Tânia; Rottinghaus, George E; Bordin, Keliani; Gomes, Gilmar A; Alvito, Paula; Assunção, Ricardo; Oliveira, Carlos A F	Assessment of mycotoxin exposure and risk characterization using occurrence data in foods and urinary biomarkers in Brazil	10.1016/j.fct.2019.03.046	Food and chemical toxicology : an international journal published for the British Industrial Biological Research Association. 2019, 128, 21-34	2019	04 : その他	01 : 原著

1338				Udovicki, Bozidar; Djekic, Ilija; Kalogianni, Eleni P; Rajkovic, Andreja	Exposure Assessment and Risk Characterization of Aflatoxin M1 Intake through Consumption of Milk and Yoghurt by Student Population in Serbia and Greece	10.3390/toxins11040205	Toxins. 2019, 11(4)	2019	04 : その他	02 : 総説
1343				Eneroth, Hanna; Wallin, Stina; Leander, Karin; Nilsson Sommar, Johan; Åkesson, Agneta	Risks and Benefits of Increased Nut Consumption: Cardiovascular Health Benefits Outweigh the Burden of Carcinogenic Effects Attributed to Aflatoxin B ₁ Exposure	10.3390/nu9121355	Nutrients. 2017, 9(12)	2017	04 : その他	01 : 原著
1347				Mojska, Hanna; Gielecińska, Iwona; Zielińska, Aleksandra; Winiarek, Joanna; Sawicki, Włodzimierz	Estimation of exposure to dietary acrylamide based on mercapturic acids level in urine of Polish women post partum and an assessment of health risk	10.1038/jes.2015.12	Journal of exposure science & environmental epidemiology. 2016, 26(3)288-95	2016	04 : その他	02 : 総説
1349				Cao, Lidong; Chen, Bo; Zheng, Li; Wang, Dongwei; Liu, Feng; Huang, Qiliang	Assessment of potential dermal and inhalation exposure of workers to the insecticide imidacloprid using whole-body dosimetry in China	10.1016/j.jes.2014.07.018	Journal of environmental sciences (China). 2015, 27, 139-46	2015	04 : その他	01 : 原著
1351				Houeto, Paul; Carton, Aude; Guerbet, Michel; Mauclore, Anne-Cécile; Gatignol, Chantal; Lechat, Philippe; Masset, Dominique	Assessment of the health risks related to the presence of drug residues in water for human consumption: application to carbamazepine	10.1016/j.yrtph.2011.11.012	Regulatory toxicology and pharmacology : RTP. 2012, 62(1)41-8	2012	04 : その他	01 : 原著
1352				Hernández, Lya G; van Steeg, Harry; Luijten, Mirjam; van Benthem, Jan	Mechanisms of non-genotoxic carcinogens and importance of a weight of evidence approach	10.1016/j.mrrev.2009.07.002	Mutation research. 2009, 682(2-3)94-109	2009	04 : その他	01 : 原著
1353				Lachenmeier, Dirk W; Gumbel-Mako, Szidonia; Sohnius, Eva-Maria; Keck-Wilhelm, Andrea; Kratz, Evamaria; Mildau, Gerd	Salivary acetaldehyde increase due to alcohol-containing mouthwash use: a risk factor for oral cancer	10.1002/ijc.24381	International journal of cancer. 2009, 125(3)730-5	2009	04 : その他	01 : 原著
1354				Crofton, K M	Bromate: concern for developmental neurotoxicity?	10.1016/j.tox.2006.01.021	Toxicology. 2006, 221(2-3)212-6	2006	04 : その他	01 : 原著
1357				Pepelko, Bill; Seckar, Joel; Harp, Paul R; Kim, James H; Gray, David; Anderson, Elizabeth L	Worker exposure standard for phosphine gas	10.1111/j.0272-4332.2004.00519.x	Risk analysis : an official publication of the Society for Risk Analysis. 2004, 24(5)1201-13	2004	04 : その他	01 : 原著
1358				Yoshida, Kikuo; Nakanishi, Junko	Estimation of dioxin risk to Japanese from the past to the future	なし	Chemosphere. 2003, 53(4)427-36	2003	04 : その他	02 : 総説
1365				Pan, Liubo; Wang, Zhou; Peng, Zhaoqiong; Liu, Guihua; Zhang, Huimin; Zhang, Jinzhou; Jiang, Jie; Pathiraja, Nimal; Xiao, Ying; Jiao, Rui; Huang, Wei	Dietary exposure to lead of adults in Shenzhen city, China	10.1080/19440049.2016.1200750	Food additives & contaminants. Part A, Chemistry, analysis, control, exposure & risk assessment. 2016, 33(7)1200-6	2016	04 : その他	01 : 原著
1374				Udovicki, Bozidar; Djekic, Ilija; Gajdos Kljusuric, Jasenka; Papageorgiou, Maria; Skendi, Adriana; Djugum, Jelena; Rajkovic, Andreja	Exposure assessment and risk characterization of aflatoxins intake through consumption of maize products in the adult populations of Serbia, Croatia and Greece	10.1080/19440049.2019.1600748	Food additives & contaminants. Part A, Chemistry, analysis, control, exposure & risk assessment. 2019, 36(6)940-951	2019	04 : その他	02 : 総説

1375				Wang, Man; Liang, Boheng; Zhang, Weiwei; Chen, Kuncai; Zhang, Yuhua; Zhou, Hongwei; Cheng, Yanfang; Liu, Huachun; Zhong, Xianwu; Li, Yingyue; Liu, Yufei	Dietary Lead Exposure and Associated Health Risks in Guangzhou, China	10.3390/ijerph16081417	International journal of environmental research and public health. 2019, 16(8)	2019	02 : 疫学データへのBMD法の適用	01 : 原著
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②論文リスト：全文入手区分1（16件）

資料 No.	著者	タイトル	DOI	書誌情報	発行年	資料のテーマ（内容） 01：疫学データにBMD法を適用する際の考え方・手順の整理 02：疫学データへのBMD法の適用 03：01及び02の両方 04：その他	文献の種類 01：原著 02：総説 03：その他
51	Braakhuis, Hedwig M; Slob, Wout; Olthof, Evelyn D; Wolterink, Gerrit; Zwart, Edwin P; Gremmer, Eric R; Rorije, Emiel; van Benthem, Jan; Woutersen, Ruud; van der Laan, Jan Willem; Luijten, Mirjam	Is current risk assessment of non-genotoxic carcinogens protective?	10.1080/10408444.2018.1458818	Critical reviews in toxicology. 2018 48(6)500-511	2018	04：その他	02：総説
58	Filipsson, Agneta Falk; Sand, Salomon; Nilsson, John; Victorin, Katarina	The benchmark dose method--review of available models, and recommendations for application in health risk assessment	10.1080/10408440390242360	Critical reviews in toxicology. 2003 33(5)505-42	2003	04：その他	02：総説
62	Davis, J Allen; Gift, Jeffrey S; Zhao, Q Jay	Introduction to benchmark dose methods and U.S. EPA's benchmark dose software (BMDS) version 2.1.1	10.1016/j.taap.2010.10.016	Toxicology and applied pharmacology. 2011 254(2)181-91	2011	04：その他	02：総説
104	Muri, Stefan D; Schlatter, Josef R; Bruschweiler, Beat J	The benchmark dose approach in food risk assessment: is it applicable and worthwhile?	10.1016/j.fct.2009.08.002	Food and chemical toxicology : an international journal published for the British Industrial Biological Research Association. 2009 47(12)2906-25	2009	04：その他	01：原著
136	Shao, Kan; Gift, Jeffrey S; Setzer, R Woodrow	Is the assumption of normality or log-normality for continuous response data critical for benchmark dose estimation?	10.1016/j.taap.2013.08.006	Toxicology and applied pharmacology. 2013 272(3)767-79	2013	04：その他	01：原著
198	Kopylev, Leonid; Fox, John	Parameters of a dose-response model are on the boundary: what happens with BMDL?	10.1111/j.1539-6924.2008.01125.x	Risk analysis : an official publication of the Society for Risk Analysis. 2009 29(1)18-25	2009	04：その他	01：原著
210	Li, X E; Lopetcharat, K; Qiu, Y; Drake, M A	Sugar reduction of skim chocolate milk and viability of alternative sweetening through lactose hydrolysis	10.3168/jds.2014-8490	Journal of dairy science. 2015 98(3)1455-66	2015	04：その他	01：原著
236	Moon, Hojin; Kim, Hyun-Joo; Chen, James J; Kodell, Ralph L	Model averaging using the Kullback information criterion in estimating effective doses for microbial infection and illness	10.1111/j.1539-6924.2005.00676.x	Risk analysis : an official publication of the Society for Risk Analysis. 2005 25(5)1147-59	2005	03：01及び02の両方	01：原著
237	Moon, Hojin; Chen, James J; Gaylor, David W; Kodell, Ralph L	A comparison of microbial dose-response models fitted to human data	10.1016/j.yrtph.2004.07.003	Regulatory toxicology and pharmacology : RTP. 2004 40(2)177-84	2004	03：01及び02の両方	01：原著
316	Thompson, Chad M; Suh, Mina; Mittal, Liz; Wikoff, Daniele S; Welsh, Brian; Proctor, Deborah M	Development of linear and threshold no significant risk levels for inhalation exposure to titanium dioxide using systematic review and mode of action considerations	10.1016/j.yrtph.2016.05.031	Regulatory toxicology and pharmacology : RTP. 2016 80,60-70	2016	04：その他	02：総説

687	Thomas, Russell S; Allen, Bruce C; Nong, Andy; Yang, Longlong; Bermudez, Edilberto; Clewell, Harvey J, 3rd; Andersen, Melvin E	A method to integrate benchmark dose estimates with genomic data to assess the functional effects of chemical exposure	10.1093/toxsci/kfm092	Toxicological sciences : an official journal of the Society of Toxicology. 2007 98(1)240-8	2007	04 : その他	01 : 原著
724	Reiss, Richard; Gaylor, David	Use of benchmark dose and meta-analysis to determine the most sensitive endpoint for risk assessment for dimethoate	10.1016/j.yrtph.2005.06.012	Regulatory toxicology and pharmacology : RTP. 2005 43(1)55-65	2005	04 : その他	01 : 原著
726	Li, Lu Xi; Chen, Li; Cao, Dan; Chen, Bing Heng; Zhao, Yan; Meng, Xiang Zhou; Xie, Chang Ming; Zhang, Yun Hui	Development of a reference dose for BDE-47, 99, and 209 using benchmark dose methods	10.3967/bes2014.108	Biomedical and environmental sciences : BES. 2014 27(9)733-9	2014	04 : その他	03 : その他
732	Leeman, Winfried R; Krul, Lisette; Houben, Geert F	Complex mixtures: relevance of combined exposure to substances at low dose levels	10.1016/j.fct.2013.03.050	Food and chemical toxicology : an international journal published for the British Industrial Biological Research Association. 2013 58,141-8	2013	04 : その他	01 : 原著
931	Brandon, E F A; Bulder, A S; van Engelen, J G M; Mahieu, C M; Mennes, W C; Pronk, M E J; Rietveld, A G; van de Ven, B M; Ten Voorde, S E C G; Wolterink, G; Slob, W; Zeilmaker, M J; Bessems, J G M	Does EU legislation allow the use of the Benchmark Dose (BMD) approach for risk assessment?	10.1016/j.yrtph.2013.07.005	Regulatory toxicology and pharmacology : RTP. 2013 67(2)182-8	2013	04 : その他	01 : 原著
1155	Woodall, George M	An exposure-response database for detailed toxicity data	10.1016/j.taap.2007.12.039	Toxicology and applied pharmacology. 2008 233(1)14-6	2008	04 : その他	02 : 総説

海外評価機関等が作成した評価書等の引用文献（27件）

引用論文番号	報告書表8海外評価機関等が作成した評価書等の引用文献のNo.	重要資料番号（報告書表10重要資料の一覧のNo.）	引用元の評価書等の番号	著者	タイトル	DOI	書誌情報	発行年	資料のテーマ（内容） 01：疫学データにBMD法を適用する際の考え方・手順の整理 02：疫学データへのBMD法の適用 03：01及び02の両方 04：その他	文献の種類 01：原著 02：総説 03：その他
引用論文1	3		23	Crump K, Viren J, Silvers A, Clewell H 3rd, Gearhart J, Shipp A.	Reanalysis of dose-response data from the Iraqi methylmercury poisoning episode	10.1111/j.1539-6924.1995.tb00345.x	Risk Anal. 1995 Aug;15(4):523-32	1995	02：疫学データへのBMD法の適用	01：原著
引用論文2	4	23	5,18,24,27	Crump KS	Calculation of benchmark doses from continuous data	なし	Risk Anal, 15(1): 79-89.	1995	01：疫学データにBMD法を適用する際の考え方・手順の整理	01：原著
引用論文3	5		4	Gearhart et al	Pharmacokinetic dose estimates of mercury in children and dose-response curves of performance tests in a large epidemiological study	なし	Water, Air, and Soil Pollution volume 80, p49-58	1995	02：疫学データへのBMD法の適用	01：原著
引用論文4	30	24	18	Wu, Y; Piegorsch, WW; West, RW; Tang, D; Petkewich, MO; Pan, W	Multiplicity-adjusted inferences in risk assessment: benchmark analysis with continuous response data	なし	Environ Ecol Stat 13:125-141	2006	01：疫学データにBMD法を適用する際の考え方・手順の整理	01：原著
引用論文5	35		10	Wheeler and Bailer	Comparing model averaging with other model selection strategies for benchmark dose estimation	なし	Environmental and Ecological Statistics, 16, 37-51	2009	02：疫学データへのBMD法の適用	01：原著
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引用論文8	52		18,27	Kodell et al	Neurotoxicity modeling for risk assessment.	10.1006/rtph.1995.1064	Regul Toxicol Pharmacol 22:24-29	1995	01：疫学データにBMD法を適用する際の考え方・手順の整理	01：原著
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引用論文10	55		10	Sand et al	Evaluation of the benchmark dose method for dichotomous data: model dependence and model selection.	10.1006/rtph.2002.1578	Regulatory Toxicology and Pharmacology, 36, 184-197.	2002	01：疫学データにBMD法を適用する際の考え方・手順の整理	01：原著
引用論文11	56		26	Araya, M et al.	Confirmation of an acute no-observed-adverse-effect and low-observed-adverse-effect level for copper in bottled drinking water in a multi-site international study.	10.1016/0272-0590(84)90107-6	Regul. Toxicol. Pharmacol., 38(3): 389-399	2003	02：疫学データへのBMD法の適用	01：原著

引用論文番号	報告書表8海外評価機関等 が作成した評価書等の引用文献のNo.	重要資料番号 (報告書表10重要資料の一覧のNo.)	引用元の評価書等の番号	著者	タイトル	DOI	書誌情報	発行年	資料のテーマ(内容) 01:疫学データにBMD法を適用する際の考え方・手順の整理 02:疫学データへのBMD法の適用 03:01及び02の両方 04:その他	文献の種類 01:原著 02:総説 03:その他
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引用論文13	58		7	Wheeler and Bailor	Properties of model-averaged BMDLs: a study of model averaging in dichotomous response risk estimation	10.1111/j.1539-6924.2007.00920.x	Risk Anal 27:659-670.	2007	03:01及び02の両方	02:総説
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引用論文15	41		7,10	Sand S, Portier CJ, Krewski D.	A signal-to-noise crossover dose as the point of departure for health risk assessment	10.1289/ehp.1003327	Environ Health Perspect. 2011 Dec;119(12):1766-74	2011	01:疫学データにBMD法を適用する際の考え方・手順の整理	01:原著
引用論文16	53		4	Gentry PR et al.	Investigation of the potential impact of benchmark dose and pharmacokinetic modeling in noncancer risk assessment, II. Investigation of impact on MRLs for methylmercury, manganese, cadmium, perchloroethylene, chloroform, and metallic mercury vapor.	10.1080/00984109708984077	ICF Kaiser Report to ATSDR. KS Crump Group, ICF Kaiser, Ruston, LA. September, 1998.	1998	01:疫学データにBMD法を適用する際の考え方・手順の整理	02:総説
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引用文献18	14		28	Karagas MR, Stukel TA, Tosteson TD.	Assessment of cancer risk and environmental levels of arsenic in New Hampshire	10.1078/1438-4639-00133	Int J Hyg Environ Health. 2002 Mar;205(1-2):85-94	2002	02:疫学データへのBMD法の適用	01:原著
引用文献19	15		10,18,27	Sand S, Filipsson AF, Victorin K.	Evaluation of the benchmark dose method for dichotomous data: model dependence and model selection	10.1006/rtph.2002.1578	Regul Toxicol Pharmacol. 2002 Oct;36(2):184-97	2002	01:疫学データにBMD法を適用する際の考え方・手順の整理	01:原著
引用文献20	17		18	Filipsson AF, Sand S, Nilsson J, Victorin K.	The benchmark dose method--review of available models, and recommendations for application in health risk assessment	10.1080/10408440390242360	Crit Rev Toxicol. 2003;33(5):505-42	2003	01:疫学データにBMD法を適用する際の考え方・手順の整理	02:総説

引用論文番号	報告書表8海外評価機関等 が作成した評価書等の引用文献のNo.	重要資料番号 (報告書表10重要資料の一覧のNo.)	引用元の評価書等の番号	著者	タイトル	DOI	書誌情報	発行年	資料のテーマ(内容) 01:疫学データにBMD法を適用する際の考え方・手順の整理 02:疫学データへのBMD法の適用 03:01及び02の両方 04:その他	文献の種類 01:原著 02:総説 03:その他
引用文献21	21		15	Yoshida T, Yamauchi H, Fan Sun G.	Chronic health effects in people exposed to arsenic via the drinking water: dose-response relationships in review	10.1016/j.taap.2003.10.022	Toxicol Appl Pharmacol. 2004 Aug 1;198(3):243-52	2004	02:疫学データへのBMD法の適用	02:総説
引用文献22	27		18	Subramaniam RP, White P, Coglianò VJ.	Comparison of cancer slope factors using different statistical approaches	10.1111/j.1539-6924.2006.00769.x	Risk Anal. 2006 Jun;26(3):825-30	2006	02:疫学データへのBMD法の適用	01:原著
引用文献23	33		14	Carlisle JC, Dowling KC, Siegel DM, Alexeeff GV.	A blood lead benchmark for assessing risks from childhood lead exposure	10.1080/10934520903139829	J Environ Sci Health A Tox Hazard Subst Environ Eng. 2009 Oct;44(12):1200-8	2009	01:疫学データにBMD法を適用する際の考え方・手順の整理	02:総説
引用文献24	37		7	Davis JA, Gift JS, Zhao QJ.	Introduction to benchmark dose methods and U.S. EPA's benchmark dose software (BMDS) version 2.1.1	10.1016/j.taap.2010.10.016	Toxicol Appl Pharmacol. 2011 Jul 15;254(2):181-91	2011	01:疫学データにBMD法を適用する際の考え方・手順の整理	02:総説
引用文献25	45		36	Gawkrodger DJ, Cook SW, Fell GS, Hunter JA.	Nickel dermatitis: the reaction to oral nickel challenge	10.1111/j.1365-2133.1986.tb06217.x	Br J Dermatol. 1986 Jul;115(1):33-8	1986	02:疫学データへのBMD法の適用	01:原著
引用文献26	46		36	Hindsén M, Bruze M, Christensen OB.	Flare-up reactions after oral challenge with nickel in relation to challenge dose and intensity and time of previous patch test reactions	10.1067/mjd.2001.110873	J Am Acad Dermatol. 2001 Apr;44(4):616-23	2001	02:疫学データへのBMD法の適用	01:原著
引用文献27	47		40	Huang LS, Cox C, Wilding GE, Myers GJ, Davidson PW, Shamlaye CF, Cernichiari E, Sloane-Reeves J, Clarkson TW.	Using measurement error models to assess effects of prenatal and postnatal methylmercury exposure in the Seychelles Child Development Study	10.1016/s0013-9351(03)00089-6	Environ Res. 2003 Oct;93(2):115-22	2003	02:疫学データへのBMD法の適用	01:原著

海外評価機関等が作成した評価書等（46件）

資料 No.	重要資料番号 (報告書表10 重要資料の一 覧のNo.)	機関	タイトル	発行年	評価書等の概要	URL	資料のテーマ (内容) 01: 疫学データにBMD法を適用する際の考え方・手順の整理 02: 疫学データへのBMD法の適用 03: 01及び02の両方 04: その他
1		ATSDR	PUBLIC HEALTH ASSESSMENT CAMP LEJEUNE DRINKING WATER U.S. : MARINE CORPS BASE CAMP LEJEUNE, NORTH CAROLINA	2017	米国海兵隊基地の飲用水に関する評価文書。本文書は、疫学データおよび再構築モデリングによる過去の汚染濃度の推定により、海兵隊基地の飲料水に含まれるベンゼンへのばく露がヒトの健康に与えた影響について評価することを目的としている。本文書ではベンゼンと人の健康影響に対する疫学調査の結果にBMD法を使用し、BMDLを算出している。	https://www.atsdr.cdc.gov/HAC/pha/MarineCorpsBaseCampLejeune/Camp_Lejeune_Drinking_Water_PHA(final)_%201-20-2017_508.pdf	02: 疫学データへのBMD法の適用
2	25	ATSDR	TOXICOLOGICAL PROFILE FOR CADMIUM	2012	カドミウムに関する利用可能な毒性学的情報及び疫学に関する情報を基に、ヒトの健康に重大なリスクをもたらすばく露レベルを含む毒性学的情報及びヒトの健康への影響に関する情報を整理・評価したものの。本文書は、カドミウムへの長期経口ばく露に伴う労働者の健康影響に関して、尿中のカドミウム濃度と腎機能の低下（尿細管性低分子タンパク尿）に係る生体指標との関連を調査した疫学研究から、生体指標がカットオフ値を上回る確率が10%上昇（excess risk）する尿中のカドミウム濃度（urinary cadmium dose, UCD10）及びその片側95%信頼下限値UCDL10を整理又は自ら算出し、検出可能なリスクを生じないとされる一日摂取量：Minimum Risk Level(MRL)を設定している。また評価に用いた各研究でBMD等の算出に使用しているモデルがATSDRでの評価に妥当か検討している。	https://www.atsdr.cdc.gov/ToxProfiles/tp5.pdf	02: 疫学データへのBMD法の適用
3	26	ATSDR	TOXICOLOGICAL PROFILE FOR MANGANESE	2012	マンガンに関する利用可能な毒性学及び疫学に関する情報を基に、ヒトの健康に重大なリスクをもたらすばく露濃度を含む毒性学的情報及びヒトの健康への影響に関する情報を整理・評価したものの。本文書は、マンガンへの長期経気道ばく露（職業ばく露）に伴う労働者の健康影響に関して、職場環境中のマンガン濃度と眼及び手の異常の発生（abnormal eye-hand coordination scoresにて判断）との関連を調査した疫学研究から、異常なスコアの過剰リスク（extra risk）が5%又は10%である環境中のマンガン濃度及びその95%信頼下限値（BMCL10及びBMCL05）を整理又は自ら算出し、MRLを設定している。	https://www.atsdr.cdc.gov/ToxProfiles/tp151.pdf	02: 疫学データへのBMD法の適用
4	27	ATSDR	TOXICOLOGICAL PROFILE FOR BENZENE	2007	ベンゼンに関する利用可能な毒性学及び疫学に関する情報を基に、ヒトの健康に重大なリスクをもたらすばく露濃度を含む毒性学的情報及びヒトの健康への影響に関する情報を整理・評価したものの。この文書では、ベンゼンへの長期経気道ばく露（職業ばく露）に伴う労働者の健康影響に関して、血中のベンゼン濃度とB細胞数の減少との関連を調査した疫学研究から、B細胞数が対照群の平均値より0.25SD低くなる血中ベンゼン濃度及びその95%信頼下限を算出し、MRLを設定している。	https://www.atsdr.cdc.gov/ToxProfiles/tp3.pdf	02: 疫学データへのBMD法の適用
5		ATSDR	Public Health Assessment Guidance Manual (2005 Update)	2005	1992年の公衆衛生評価ガイダンスマニュアルの改訂版。このガイダンスマニュアルは、有害な廃棄物の公衆衛生への影響を評価するための論理的なアプローチを提供し、健康評価における最新かつ最適な評価方法の適用を目的としている。Chapter 8で健康評価にBMD法を適用する条件等を述べ、BMD法を用いたリスク評価法について述べている。	https://www.atsdr.cdc.gov/hac/phamanual/pdfs/phagm_final1-27-05.pdf	01: 疫学データにBMD法を適用する際の考え方・手順の整理
6		ATSDR	Toxicological profile for Mercury	1999	水銀の毒性プロファイル。この文書は水銀へのばく露による健康リスクを検討し、毒性評価することを目的としている。文書中では疫学データにBMD法を適用してBMDLを算出し最小リスクレベルを推定した研究を紹介している。	https://www.atsdr.cdc.gov/toxprofiles/tp46.pdf	02: 疫学データへのBMD法の適用
7	28	CDC/NIOSH	Criteria for a Recommended Standard: Occupational Exposure to Diacetyl and 2,3-Pentanedione	2016	ジアセチルと2,3-ペンタンジオンに関する全ての関連文献を基に、ばく露特性の研究とばく露低減技術について説明し、適切なリスク管理の推奨事項を確立するための理論的根拠と基準を整理したもの。この文書では、ジアセチルと2,3-ペンタンジオンへの長期経気道ばく露（職業ばく露）に伴う労働者の健康影響について、職場環境中のジアセチルと2,3-ペンタンジオン濃度と肺機能低下（FEV1で比較）との関連を調査した疫学研究から、10年後及び45年後のEEV1有病率がカットオフ値を上回る可能性が0.1%上昇する（1/1000 excess prevalence after 45 years）ジアセチルと2,3-ペンタンジオン濃度を算出している。	https://www.cdc.gov/niosh/docs/2016-111/default.html	02: 疫学データへのBMD法の適用
8		Thailand	Comments submitted by Thailand Agenda Item 3 Thailand information paper On estimating the risk of developing histamine poisoning from the consumption Thai fish sauces	2011	本文書は、魚醤中のヒスタミンを制御するためのガイドラインの基礎データとして、タイおよびオーストラリアの疫学データから、タイの魚醤摂取によるヒスタミン中毒を発症するリスクを調査することを目的としている。本文書では魚醤の摂取によるヒスタミン中毒の潜在的なリスクを調査し、動物実験から算出したNOAELと人の疫学調査の結果にBMD法を適用し算出したBMDLから参照用量（RfD）を推定、消費者のリスクを推定している。	http://www.fao.org/tempref/codex/Metings/CCFFP/ccffp31/CRD/CRD_18_Thailand.pdf	02: 疫学データへのBMD法の適用
9	29	NRC (National Research Council)	Toxicological effects of methylmercury	2000	メチル水銀に関する利用可能な毒性学及び疫学に関する情報を基に、許容可能なばく露濃度を含む毒性学的情報及びヒトの健康への影響に関する情報を整理・評価。この文書ではメチル水銀への経胎盤ばく露に伴う小児への健康影響について、母親のメチル水銀への長期経口ばく露（母親の毛髪及び臍帯血中のメチル水銀濃度）と出生後の小児の神経発達との関連を調査した出生コホート研究から、神経発達のリスクが5%増加するメチル水銀濃度及びその95%信頼下限を算出し、参照用量を検討している。	https://www.ncbi.nlm.nih.gov/books/NBK225778/	02: 疫学データへのBMD法の適用

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10		DEFRA	Defining a point of departure and potency estimates in carcinogenic dose response	2018	発がん性物質へのばく露に関連するPOD等の推定値を導き出すための様々な方法の概要を紹介することを目的とした文書。本文書では、動物及び人の用量反応データからBMD等のPODやTD25、TD50等の推定値を導出する方法、及び発がん性の推定にBMD法等を使用する方法を整理している。	https://www.gov.uk/government/publications/carcinogenic-dose-response-defining-a-point-of-departure-and-potency-estimates	01: 疫学データにBMD法を適用する際の考え方・手順の整理
11	10	EFSA	Draft for internal testing Scientific Committee guidance on appraising and integrating evidence from epidemiological studies for use in EFSA's scientific assessments	2020	EFSAの評価において、疫学研究から得られるエビデンスの評価、統合の考え方を整理したガイダンスであり、以下の内容を含む。 ・デザイン別疫学研究の概要 (典型的なバイアス含む) の紹介 ・エビデンスの評価に関連する重要な疫学上の概念の説明 ・研究の信頼性 (の評価) に関して、関連性の尺度、ばく露評価、統計学的推論、systematic error及びeffect modificationの解説 ・研究の適用可能性 (の評価) に関して、外部妥当性の概念の解説 ・疫学研究の評価の原則を提示するとともに、内的妥当性の評価及び研究内容の批判を行うためのrisk of bias (RoB) toolを用いた評価の手順 (ディンジョンツリー) の概説 ・RoB toolを使用した介入研究及び観察研究の評価の例示	https://www.efsa.europa.eu/en/efsajournal/pub/6221	04: 疫学研究から得られた情報をリスク評価で用いる場合の評価、統合の考え方の整理
12	30	EFSA	Risk to human health related to the presence of perfluoroalkyl substances in food	2020	複数の化合物への複合ばく露を評価するための最近のガイダンスに従い、主なパーフルオロアルキル化合物 (PFAS) の耐容週間摂取量 (TWI) を含む毒性学的情報及び健康への影響に関する情報を整理・評価。食品中のPFASへの長期経口ばく露に伴う小児の健康影響について、血清中のPFAS濃度とジフテリア、破傷風、及びヘモフィルス・インフルエンザ菌 (b型) に対する抗体価の低下との関連を調査した疫学研究から、対照群と比較して抗体価が10%低下する血清中のPFAS濃度とその90%信頼区間を算出し、健康影響に基づく指標値 (HBGV) を設定している。	https://www.efsa.europa.eu/en/efsajournal/pub/6223	02: 疫学データへのBMD法の適用
13	31	EFSA	Update of the risk assessment of nickel in food and drinking water	2020	ニッケルに関する利用可能な毒性学及び疫学に関する新たな情報・ガイダンスを基に、慢性及び急性の、食事を介したばく露量を含む毒性学的情報及びヒトの健康への影響に関する情報を整理・評価。ニッケルへの短期経口ばく露に伴う成人の健康影響に関して、ニッケルの経口摂取と全身性接触皮膚炎の発症との関連を調査した介入研究から、全身性接触皮膚炎の発症率が10%増加するニッケルのばく露量とその95%信頼下限を算出している。算出した95%信頼下限をReference pointとするか検討されたが、最終的にNOAEL/LOAEL法に基づきReference pointが設定された。	https://www.efsa.europa.eu/en/efsajournal/pub/6268	02: 疫学データへのBMD法の適用
14	32	EFSA	SCIENTIFIC OPINION Risk to human health related to the presence of perfluorooctane sulfonic acid and perfluorooctanoic acid in food	2018	パーフルオロオクタンスルホン酸 (PFOS) とパーフルオロオクタン酸 (PFOA) に関する食品試料分析とヒトの疫学研究を基に、耐容週間摂取量 (TWI) を含む毒性学的情報及びヒトの健康への影響に関する情報を整理・評価。この文書ではパーフルオロオクタンスルホン酸 (PFOS) 及びパーフルオロオクタン酸 (PFOA) への長期ばく露 (経口ばく露、経気道ばく露、経胎盤ばく露) に伴う成人及び小児の健康影響について、血漿中のPFOSと総コレステロールの増加、出生体重の低下、小児におけるワクチン接種後の抗体価の減少、又はPFOA濃度と総コレステロールの増加、血清ALT値の増加、出生体重の減少との関連を調査した疫学研究から、アウトカムを5%変化させる血漿中のPFOS及びPFOA濃度とその95%信頼下限を算出し、HBGVを設定している。	https://www.efsa.europa.eu/en/efsajournal/pub/5194	02: 疫学データへのBMD法の適用
15	5	EFSA	Update: use of the benchmark dose approach in risk assessment	2017	BMRの設定に係る課題、数理モデルの選択方法等を整理したガイダンス。本文書は、2009年に発行されたBMD法のガイダンスの更新版であり、以下の内容を含む。 ・ハザードの特定方法 (重要なエンドポイントの選択方法) を説明 ・ハザードの特性評価における用量反応データ (NOAEL法及びBMD法) の使用方法と解釈を説明。 ・ハザードの特性評価 (遺伝毒性及び発がん物質のリスク評価、食品添加物と残留農薬の許容一日摂取量 (ADI)、ばく露マージン (MOE)、耐用一日摂取量 (TDI)、耐容週間摂取量 (TWI)) の設定方法を説明 ・BMD法の適用方法を説明 なお、BMD法は試験動物データや疫学データに用いることが可能だが、本ガイダンスでは疫学データに関して扱っておらず、EFSAの別のガイダンスの対象である。	https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2017.4658	01: 疫学データにBMD法を適用する際の考え方・手順の整理
16		EFSA	Scientific Opinion on the risks to animal and public health and the environment related to the presence of nickel in feed	2015	飼料に含まれるニッケルに対するCONTAMパネルの科学的見解。飼料中のニッケルが動物および人の健康、環境へ及ぼす影響について評価することを目的とし動物実験および疫学調査から人への影響を推計している。本文書では、疫学調査の結果にBMD法を使用し、ニッケルへ経口ばく露後の全身性接触皮膚炎の発生率からBMDLを算出している。	https://www.efsa.europa.eu/en/efsajournal/pub/4074	02: 疫学データへのBMD法の適用
17	33	EFSA	Scientific Opinion on the risks to public health related to the presence of nickel in food and drinking water	2015	ニッケルに関する食品・飲料水試料分析、ヒト及び試験動物における毒性データを基に、急性・慢性のばく露量レベルを含む毒性学的情報及びヒトの健康への影響に関する情報を整理・評価。この文書では、食品及び飲料水に含まれるニッケルへの短期経口ばく露に伴う成人の健康影響について、血清中及び尿中のニッケル濃度と全身性接触皮膚炎の発症との関連を調査した疫学研究から、全身性皮膚炎を発生する確率が10%増加するニッケル濃度とその95%信頼下限を算出し、Reference pointを設定している。	https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4002	02: 疫学データへのBMD法の適用

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18		EFSA	Scientific Opinion on health benefits of seafood (fish and shellfish) consumption in relation to health risks associated with exposure to methylmercury	2014	メチル水銀と関連する魚介類に対するCONTAMパネルの科学的見解。魚介類の消費と魚介類に含まれるメチル水銀による人の健康に及ぼす影響を評価することを目的としている。本文書では、2011年に疫学調査にBMD法を適応し、胎児の神経発達に影響を及ぼすBMDLを算出したことを紹介している。	https://www.efsa.europa.eu/en/efsajournal/pub/3761	02: 疫学データへのBMD法の適用
19	34	EFSA	Scientific Opinion on the risk for public health related to the presence of mercury and methylmercury in food	2012	水銀に関する食品試料分析結果を基に、許容可能なばく露濃度を含む毒性学的情報及びヒトの健康への影響に関する情報を整理・評価。本文書は、メチル水銀への経胎盤ばく露に伴う小児の健康影響について、母親の毛髪中のメチル水銀濃度と出生後の小児の神経系への影響（言語力、記憶力、運動能力、知覚運動、行動機能）との関連を調査した疫学研究から、神経系への影響が5%増加する母親の毛髪中のメチル水銀とその95%信頼下限を算出し、耐容週間摂取量（TWI）を算出している。	https://www.efsa.europa.eu/en/efsajournal/pub/2985	04: その他
20	35	EFSA	SCIENTIFIC / TECHNICAL REPORT submitted to EFSA An international pooled analysis for obtaining a benchmark dose for environmental lead exposure in children	2010	7つのコホート研究を用いてプール解析を実施し、低用量の鉛へのばく露が小児の知的機能に及ぼす影響を調査。この文書では鉛への経口ばく露に伴う健康影響について、鉛へのばく露と小児の知能指数の低下（Full Scale IQ scoreを測定）の関連を調査したプール解析から、IQスコアを1%変化させる鉛濃度とその95%信頼下限を算出している。	https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2010.EN-47	02: 疫学データへのBMD法の適用
21	36	EFSA	Scientific Opinion on Lead in Food	2010	成人及び小児において、食事を介してばく露する鉛が重大な健康リスクを引き起こすか評価しており、リスク評価の重大な影響として、小児の発達神経毒性と成人の心血管系及び腎臓への影響を特定している。この文書では、鉛へのばく露に伴う小児の健康影響について、血中の鉛濃度と小児の神経発達への影響（Full Scale IQ scoreを測定）、鉛への経口ばく露及び経気道ばく露に伴う成人の健康影響について、血中の鉛濃度と心血管系への影響（血圧の上昇）及び腎臓への影響（タンパク尿）との関連を調査した疫学研究から、IQスコアを1%減少させる鉛濃度とその95%信頼下限、血圧を1%上昇させる鉛濃度とその95%信頼下限、CKDの有病率を10%上昇させる鉛濃度とその95%信頼下限を算出している。これらの信頼下限からReference pointを設定している。	https://www.efsa.europa.eu/en/efsajournal/pub/1570	02: 疫学データへのBMD法の適用
22		EFSA	Guidance of the Scientific Committee on use of the benchmark dose approach in risk assessment.	2009	リスク評価にベンチマークドーズ法を使用する際のガイダンス。この文書では、従来使用されていたNOAEL法の代替としてベンチマークドーズ法を使用する必要があるか、またどのような状況下での使用が適切か、推奨事項を示しており、以下の内容を含む。またこのガイダンスは2017年に更新されている。 ・ハザードの特定方法（重要なエンドポイントの選択方法）を説明 ・ハザードの特性評価における用量反応データ（NOAEL法およびベンチマークドーズ法）の使用方法和解釈を説明。 ・ハザードの特性評価（遺伝毒性および発がん性物質のリスク評価、食品添加物と残留農薬の許容一日摂取量（ADI）、ばく露マージン（MOE）、耐用一日摂取量（TDI）、耐容週間摂取量（TWI）の設定方法を説明 ・ベンチマークドーズ法の適用養蜂を説明	https://www.efsa.europa.eu/en/efsajournal/pub/1150	01: 疫学データにBMD法を適用する際の考え方・手順の整理
23	37	EFSA	Scientific Opinion on Arsenic in Food	2009	食品中のヒ素に関する100,000件以上の実態データを考慮し、食品中のヒ素がヒトの健康に及ぼすリスク評価を実施、平均的な住民のばく露量を推定し、暫定耐容週間摂取量（PTWI）を設定している。この文書ではヒ素への経口ばく露に伴う成人の健康影響について、飲料水中のヒ素濃度と健康への悪影響（皮膚病変、膀胱がん、肺がん）との関連を調査した疫学研究から、健康への悪影響が発生する確率が1%上昇する（excess risk）飲料水中のヒ素濃度とその95%信頼下限を算出し、reference pointを設定している	https://www.efsa.europa.eu/en/efsajournal/pub/1351	02: 疫学データへのBMD法の適用
24	38	EFSA	SCIENTIFIC OPINION Cadmium in food - Scientific opinion of the Panel on Contaminants in the Food Chain	2009	本文書は、食品を介するカドミウムへのばく露と尿中のカドミウム濃度に関する最新の疫学研究を用いて、食品中のカドミウムにばく露することによるヒトの健康リスクを評価している。この文書ではカドミウムへの経口ばく露に伴う成人の健康影響について、尿中のカドミウム濃度と腎機能の低下に係る生体指標（urinary beta-2-microglobulin）との関連を調査した疫学研究から、生体指標がカットオフ値を上回る確率を5%増加させる（extra risk）尿中のカドミウム濃度とその95%信頼下限を算出している。	https://www.efsa.europa.eu/en/efsajournal/pub/980	02: 疫学データへのBMD法の適用
25	39	EFSA	TECHNICAL REPORT OF EFSA Meta-analysis of Dose-Effect Relationship of Cadmium for Benchmark Dose Evaluation	2009	尿中のカドミウム濃度とカドミウムの毒性を示す腎臓又は骨の生体指標との関連を調査した科学的文献のシステマティックレビューを実施している。カドミウムへのばく露に伴う健康影響評価について、尿中のカドミウム濃度と腎機能の低下に係る生体指標（β2-MG concentration in urine）との関連を調査し、生体指標がカットオフ値を上回る確率が5%又は10%上昇する（excess risks）尿中のカドミウム濃度とその片側95%信頼下限を算出している。	https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2009.254r	02: 疫学データへのBMD法の適用
26		EFSA	Opinion of the Scientific Panel on contaminants in the food chain [CONTAM] related to mercury and methylmercury in food	2004	食品中の水銀とメチル水銀に関連するCONTAMパネルの科学的見解。水銀とメチル水銀で汚染された食品の消費による人の健康への影響を評価することを目的としている。本文書では、JEFCが疫学研究の結果にBMD法を使用し、胎児の神経毒性に対してBMDLを算出した研究を紹介している。	https://www.efsa.europa.eu/en/efsajournal/pub/34	02: 疫学データへのBMD法の適用

資料 No.	重要資料番号 (報告書表10 重要資料の一覧のNo.)	機関	タイトル	発行年	評価書等の概要	URL	資料のテーマ (内容) 01: 疫学データにBMD法を適用する際の考え方・手順の整理 02: 疫学データへのBMD法の適用 03: 01及び02の両方 04: その他
27	6	EPA	Benchmark Dose Technical Guidance	2012	化学物質へのばく露に対するリスク評価にBMD法を適用するためのガイダンスであり、以下の内容を含む。 ・BMD法に使用する疫学研究から得た情報 (研究デザイン、モデリングする研究及びエンドポイント、BMDを算出するためのデータセット) の選択方法を説明 ・使用するデータ (二値データ、連続値データ) に適したBMRの選択方法を説明 ・疫学研究から得た情報を用いたモデリング手法 (モデルの選択方法、モデルが使用したデータセットに適応しているか評価する方法、BMDLを取得するための信頼限界の算出方法、PODの算出に使用するモデルの選択方法) を説明 このガイダンスでは、ヒトの毒性学データをモデリングする機会は限られており、ヒトを対象とした研究は動物試験ほど標準化されていないとしている。したがって、疫学データのモデリングは個別に行われる必要がある。また疫学データをモデリングするには共変量の調整を行う必要もある。	https://www.epa.gov/sites/production/files/2015-01/documents/benchmark_dose_guidance.pdf	01: 疫学データにBMD法を適用する際の考え方・手順の整理
28	40	EPA	Fluoride: Dose-Response Analysis For Non-cancer Effects. Health and Ecological Criteria Division Office of Water	2010	2006年のNational Research Council (NRC)の報告に応え、フッ素化合物に関する入手可能な疫学研究を使用し、飲料水中のフッ素化合物がヒトの健康に及ぼす用量を再評価している。この文書はフッ素化合物への経口ばく露に伴う小児の健康影響について、飲料水中のフッ素化合物と重度のフッ素症発症との関連を調査した疫学研究から、フッ素症を発生する確率が0.5%、1%、5%増加する飲料水中のフッ素化合物濃度とその95%信頼下限を算出している。	https://www.epa.gov/sdwa/fluoride-exposure-and-relative-source-contribution-analysis-documents	02: 疫学データへのBMD法の適用
29	7	EPA	Guidelines for Carcinogen Risk Assessment	2005	発がん物質のリスク評価ガイドライン。ハザード分析を行うために必要な条件や分析方法を整理しており、以下の内容を含む。 ・ハザードの評価方法 (特性評価の概要、評価に使用する疫学研究又は動物試験から得た情報の精査、作用機序の評価、証拠の重み付け) を説明 ・リスク評価における用量反応評価 (用量の分析方法、観察範囲の解析、低用量へ外挿する方法、様々なヒトへのばく露における外挿) を説明。ここではBMD法を用いて算出したBMDLをPODに設定することを検討している。 ・発がん性リスク評価に関連する問題に重点を置いて、ばく露評価の原則を説明	https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment	01: 疫学データにBMD法を適用する際の考え方・手順の整理
30	41	EPA	TOXICOLOGICAL REVIEW OF BENZENE (NONCANCER EFFECTS) (CAS No. 71-43-2) In Support of Summary Information on the Integrated Risk Information System (IRIS)	2002	本文書は、公開された関連する科学文献をレビューし、主要な研究を評価することで、ベンゼンのばく露による非がん影響を定性的及び定量的に特徴づけ、参照用量及び参照濃度を設定している。この文書ではベンゼンへの長期経口ばく露及び経気道ばく露に伴う労働者の健康影響について、職場環境中のベンゼン濃度と血液毒性に係る生体指標 (リンパ球数) との関連を調査した疫学研究から、リンパ球数が対照群の平均値より1SD低くなる職場環境中のベンゼン濃度とその95%信頼下限を算出し、参照用量に使用されるPODを設定している。	https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0276tr.pdf	02: 疫学データへのBMD法の適用
31	42	EPA	integrated Risk Information System (IRIS) Chemical Assessment Summary Methylmercury (MeHg); CASRN 22967-92-6	2001	メチル水銀のヒトの健康に対する影響評価であり、経口参照用量の算出と発がん性評価を実施している。経口参照用量は疫学研究から得られたデータにBMD法を適用して算出している。本文書は、メチル水銀への経胎盤ばく露に伴う小児の健康影響について、母親の毛髪中又は臍帯血中のメチル水銀濃度と小児の出生後の神経発達への影響を調査した疫学研究から、神経発達への悪影響が5%増加する母親の毛髪中又は臍帯血中のメチル水銀濃度とその95%信頼下限を算出、参照用量を設定している。	https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0073_summary.pdf	02: 疫学データへのBMD法の適用
32	43	EPA	Water Quality Criterion for the Protection of Human Health: Methylmercury Chapter 4: Risk Assessment for Methylmercury	2001	メチル水銀の環境水質基準 (Ambient Water Quality Criterion (AWQC)) の基礎であり、ヒトの健康を保護するための環境水質基準の方法論 (Methodology for Deriving ambient Water Quality Criteria for the Protection of Human Health. 2000 Human Health Methodology, U.S. EPA) に記載されている新しい方法と新たに入手した情報を使用して水質基準を設定している。本文書は、メチル水銀への経胎盤ばく露に伴う小児の健康影響について、母親の毛髪中又は臍帯血中のメチル水銀濃度と出生後の小児の神経発達への影響を調査した疫学研究から、小児の神経発達への悪影響を5%増加させる母親の毛髪中又は臍帯血中のメチル水銀濃度とその95%信頼下限を算出し、参照用量を設定している。	https://clu-in.org/download/contaminantfocus/mercury/water-quality-criterion-methylmercury.pdf	02: 疫学データへのBMD法の適用
33		EPA	The use of the benchmark dose approach in health risk assessment.	1995	本文書は参照用量 (RfD) 及び参照濃度 (RfC) の計算にベンチマークドーズ法を適用する際の手順等を説明している。この文書は以下の内容を含む。 ・ベンチマークドーズ法の概要 ・ベンチマークドーズ法の詳細な説明 (BMRを選択するための基準、モデルに使用するデータの種類の種類、数理モデルを選択する基準、選択したモデルの適合、増加したリスクの測定方法、Benchmark Levelの選択、信頼区間の計算、適切なBMDの選択、考慮すべき不確実性) ・NOAELとBMDの詳細に比較 (概念、相対的なサイズ、研究デザインによって課せられる制約、対照群数と分布、用量反応に関する情報の組み込み (INCORPORATION)、データの解釈、モデルの感度、リスクの定量推定) ・BMDに関連する研究ニーズを要約。	https://hero.epa.gov/hero/index.cfm/reference/details/reference_id/5992	01: 疫学データにBMD法を適用する際の考え方・手順の整理

資料 No.	重要資料番号 (報告書表10 重要資料の一覧のNo.)	機関	タイトル	発行年	評価書等の概要	URL	資料のテーマ (内容) 01: 疫学データにBMD法を適用する際の考え方・手順の整理 02: 疫学データへのBMD法の適用 03: 01及び02の両方 04: その他
35	45	FDA	A Quantitative Assessment of Inorganic Arsenic in Apple Juice (DRAFT REPORT)	2013	米国の全国健康栄養調査 (NHANES) による食事摂取量データや、リンゴジュースからサンプリングした無機ヒ素を分析したデータを基に、リンゴジュース中の無機ヒ素による長期的ながんリスクを定量・推定している。この文書では、井戸水中のヒ素濃度と発がん (肺がん、尿路がん) との関連を調査した疫学研究から、発症率が増加するヒ素濃度とその信頼区間 (5%及び95%) を算出している。	https://www.fda.gov/media/86075/download	02: 疫学データへのBMD法の適用
36		Health Canada	Health Risk Assessment of Dietary Exposure to Cadmium	2018	カドミウムの危険性、食品に含まれるカドミウム量、カドミウムが含まれる食品の消費に関連する科学的情報を使用して、カドミウムの包括的な食事健康リスクを評価。この文書はカドミウムへの経口ばく露に伴う健康影響について、EFSAおよびJECFAのリスク評価書を参照している。	—	02: 疫学データへのBMD法の適用
37	8	WHO	Environmental Health Criteria 239 Principles for modelling dose-response for the risk assessment of chemicals	2009	用量反応評価において、用量反応データに数理モデルを当てはめる際の考え方や手順を解説したガイダンス。本文書は以下の内容を含む。 ・リスクの分析方法及び評価方法の概説 ・用量反応モデリングの基本概念的説明 ・用量反応モデリングの歴史的展望や考慮すべき事項を説明 ・用量反応モデリングを行う際の原則 (選択するデータの種類の種類、モデルの種類、使用するデータの分布の検討、モデルの適合とパラメータの推定、モデルの比較、不確実性の確認) について説明 ・算出した結果の報告	https://apps.who.int/iris/handle/10665/43940	01: 疫学データにBMD法を適用する際の考え方・手順の整理
38	46	JECFA	Safety evaluation of certain contaminants in food. Prepared by the Seventy-second meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). WHO Food Additives Series: 63. FAO JECFA Monographs 8. Perchlorate	2011	第72回JECFA会合における過塩素酸塩のリスク評価結果を基に整理されたモノグラフである。本文書は、飲料水等を介した過塩素酸塩の短期経口ばく露に伴う成人の健康影響について、飲料水中のヒ素濃度と甲状腺への影響 (甲状腺のヨウ素の取込み量を測定) との関連を調査したと介入研究から、ヨウ素の取込みを50%阻害する飲料水中のヒ素濃度とその95%信頼下限を算出している。。	https://apps.who.int/iris/bitstream/handle/10665/44520/9789241660631_eng.pdf?sequence=1	02: 疫学データへのBMD法の適用
39	47	JECFA	Safety evaluation of certain contaminants in food Prepared by the Seventy-second meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) ARSENIC (addendum) (pages 153 – 316) WHO Food Additives Series: 63. FAO JECFA Monographs 8.	2011	第72回JECFA会合におけるヒ素のリスク評価結果を基に整理されたモノグラフである。本文書は、飲料水を介したヒ素への長期経口ばく露に伴う成人の健康影響について、飲料水中のヒ素濃度と泌尿器がん、肺がん、皮膚病変との関連を調査した疫学研究から、発症率が5%増加する飲料水中のヒ素濃度とその95%信頼下限を算出している。	https://apps.who.int/food-additives-contaminants-jecfa-database/chemical.aspx?chemID=1863	02: 疫学データへのBMD法の適用
40	48	JECFA	Safety evaluation of certain food additives and contaminants Prepared by the Seventy-third meeting of the Joint FAO/WHO Expert Committee on Food Additives(JECFA) WHO Food Additives Series: 64 Safety evaluations of groups of related flavouring agents, Contaminants Cadmium	2011	本文書は、第73回JECFA会合におけるカドミウムのリスク評価を基に整理されたモノグラフである。カドミウムへの経口ばく露に伴う成人の健康影響について、尿中のカドミウム濃度と腎機能障害 (低分子タンパク質) の生体指標との関連を調査した疫学研究から、生体指標がカットオフ値を上回る確率が5%又は10%となる尿中のカドミウム濃度とその95%信頼下限を算出し、ブレイクポイント (breakpoint) を設定している。	https://apps.who.int/iris/bitstream/handle/10665/44521/9789241660648_eng.pdf?sequence=1	02: 疫学データへのBMD法の適用
41	49	JECFA	Safety evaluation of certain food additives and contaminants. Prepared by the Sixty-seventh meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) WHO Food Additives Series: 58 Food additives, Food additives	2007	第67回JECFA会合におけるメチル水銀のリスク評価結果を基に整理されたモノグラフである。本文書は、メチル水銀への経胎盤ばく露に伴う小児の健康影響について、母親の毛髪中及び臍帯血中のメチル水銀濃度と脳幹聴覚誘発電位 (brainstem auditory evoked potentials (BAEP)) の関連を調査した疫学研究から、BAEPを発症する確率が5%増加する母親の毛髪中及び臍帯血中のメチル水銀濃度とその95%信頼下限を算出した研究を紹介している。	https://apps.who.int/iris/bitstream/handle/10665/43645/9789241660587_eng.pdf?sequence=1	02: 疫学データへのBMD法の適用
42	50	JECFA	Safety evaluation of certain food additives and contaminants Prepared by the Sixty-first meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) WHO Food Additives Series: 52 Methyl Mercury	2004	本文書は第61回JECFA会合におけるメチル水銀のリスク評価結果を基に整理されたモノグラフである。本文書は、メチル水銀への経胎盤ばく露に伴う小児の健康影響について、母親の毛髪中及び臍帯血中のメチル水銀濃度と小児の神経発達との関連を調査した疫学研究より、神経発達への影響 (異常の増加率) が2%、5%、10%となる母親の毛髪中のメチル水銀濃度とその95%信頼下限を算出した研究を紹介している。	https://apps.who.int/iris/bitstream/handle/10665/43038/924166052X.pdf?sequence=1&isAllowed=y	02: 疫学データへのBMD法の適用
43		RIVM	Loodinname via kraanwater Blootstellingschatting en risicobeoordeling voor diverse risicogroepen RIVM Briefrapport 2019-0090	2019	水道水中の鉛を摂取することによる人のリスク評価を実施している。この文書では水道水中の鉛濃度からばく露量を推定、住民の健康への影響を評価している。鉛ばく露のリスク評価としてEFSAのリスク評価書 (2010) を参照している。	https://www.rivm.nl/bibliotheek/rapporten/2019-0090.pdf	02: 疫学データへのBMD法の適用

資料 No.	重要資料番号 (報告書表10重要資料の一覧のNo.)	機関	タイトル	発行年	評価書等の概要	URL	資料のテーマ (内容) 01: 疫学データにBMD法を適用する際の考え方・手順の整理 02: 疫学データへのBMD法の適用 03: 01及び02の両方 04: その他
44	9	WHO	EHC240: Principles and Methods for the Risk Assessment of Chemicals in Food CHAPTER 5. DOSE-RESPONSE ASSESSMENT AND DERIVATION OF HEALTH-BASED GUIDANCE VALUES Second edition (2020)	2020	食品中の化学物質のリスク評価を示したガイダンスの第5章であり、用量反応評価について示している。本文書は以下の内容を含む。 ・用量反応評価の基本概念の説明 ・BMD法の実施方法、特にモデリング方法（使用するデータの適合性の確認、モデルの選択、モデルの仮定、モデルのフィッティング及びパラメータの推定、モデルの不確実性と平均化、モデルパラメータの制約、適合したモデルの評価）について説明 ・モデルに使用する研究デザイン及びデータの妥当性を確認する方法を整理 ・NOAEL法及びBMD法からPODを算出する方法を説明 ・HBGVを確立する方法を説明 ・MOEアプローチを説明	http://www.inchem.org/documents/ehc/ehc/ehc240_index.htm	01: 疫学データにBMD法を適用する際の考え方・手順の整理
45		WHO	Prioritizing hazardous pollutants in two Nigerian water supply schemes: a risk-based approach	2013	本文書はリスクベースアプローチを使用し、ナイジェリアの飲料水中に含まれる汚染物質（化学物質）を調査、優先的に除去すべき化学物質を特定することを目的としている。本文書では化学物質の毒性評価にBMD法の使用を提案、BMDLを元に影響評価を実施している。※BMDLは別途調査研究を参照としている。本文書中に、具体的な数値を用いた算出方法の記載がないが、referenceに記載されていると考えられる。	https://www.who.int/bulletin/volumes/91/8/12-115774/en/	02: 疫学データへのBMD法の適用
46		JECFA	Safety evaluation of certain food additives and contaminants Prepared by the Seventy-third meeting of the Joint FAO/WHO Expert Committee on Food Additives(JECFA) WHO Food Additives Series: 64 Safety evaluations of groups of related flavouring agents, Contaminants Lead	2011	本文書は、第73回JECFA会合における食品添加物および汚染物質のリスク評価を基に整理された基に整理されたモノグラフである。 この文書では鉛へのばく露に伴う小児の健康影響について、血中の鉛濃度と神経発達発達（IQスコアの低下）の関連を調査した疫学研究から、IQスコアを1ポイント低下させる血中の鉛濃度と95%信頼下限を算出した研究を紹介している。	https://apps.who.int/iris/bitstream/handle/10665/44521/9789241660648_eng.pdf?sequence=1	02: 疫学データへのBMD法の適用
47		WHO	GUIDANCE DOCUMENT ON EVALUATING AND EXPRESSING UNCERTAINTY IN HAZARD CHARACTERIZATION	2018	本文書は特定のハザード特性評価における重要な不確実性を定量的に評価し、調査研究の最終的な結果と調査させて表現する方法を提供することを目的としたガイダンスである。また、特定の不確実性を通知するための情報が不足しているために、定量化することができない不確実性に対応する方法も提供している。この文書で提供する方法論は、用量反応に関する情報が入手可能な単一の化学物質へのばく露に焦点を当てている。	https://apps.who.int/iris/handle/10665/259858	04: その他