

Explanatory note, related to Biocidal Products Regulation (EU) No528/2012

How to read the Guidance on data sharing

As per Article 63(1) and (4) of the BPR, applicants shall "make every effort to reach an agreement [with data owners] on the sharing of the data" and "compensation for data sharing shall be determined in a fair, transparent and non-discriminatory manner". Reference is made to the Guidance on data sharing established by the Agency (in accordance with Regulation 1907/2006 (REACH)).

To support the reader, ECHA has issued this short note clarifying which chapters are of relevance to the applicants under Biocidal Products Regulation (EU) No528/2012 (BPR), so that the reader is directed to the chapters that are relevant to him.

Chapter		Page	Relevance	
1	Introduction			
1.2.5	Inquiry prior to registration	15	Yes	Similarity with Art 62
1.2.8	Data sharing disputes	17	Partially	Art 27(5) is similar to Art 63(3) of the BPR Regulation
1.3	Key principles for data sharing	18	Yes	Also to be applied under the BPR Regulation
2	Legal framework: relevant legal provisions			
2.5	Competition rules	23	Yes	Other legislations need to be considered
3	Data sharing for phase-in substances			some aspects may be of relevance
3.3.1	Overall approach to data sharing	43	Partially	
3.3.3	The collective route	45	Partially	
3.3.3.1	Step 1: Individual gathering of available information	48	Partially	
3.3.3.2	Step 2: Agreement on the form of cooperation/cost sharing mechanism	48	Partially	
3.3.3.3	Step 3: Collection and Inventory creation of information available to potential registrants	49	Partially	
3.3.3.4	Step 4: Evaluation of available information within the SIEF	49	Partially	
3.3.3.5	Step 5: Consideration of information requirements	51	Partially	
3.3.3.6	Step 6: Identification of data gaps and collection of other available information	52	Partially	
3.3.3.8	Step 8: Sharing of the cost of the data	54	Yes	
3.3.5	Data Sharing: Individual route (opt-out)	61	Partially	some aspects may be of relevance
3.4.3	How to conduct negotiations in order to prevent data sharing disputes	73	Yes	
4	The inquiry process	78	Partially	
4.1	The purpose of the inquiry process	78	Yes	Purposes and principles are similar; hence, some aspects may be of relevance. Reference is made to the Inquiry page under the BPR Regulation
4.2	Is it obligatory to follow the inquiry process?	78	Yes	
4.6	Outcomes of the inquiry process	81	Partially	

Chapter		Page	Relevance	
4.7	Data sharing between registrants following an inquiry	84	Partially	
4.9	Data sharing disputes after an inquiry	91	Yes	
4.9.1	Data sharing dispute according to Article 27(5), including Figure 12	91	Yes	
4.9.2	How to conduct negotiations in order to prevent data sharing disputes?	93	Yes	
5	Cost sharing			
5.1	Introduction	96	Yes	
5.2	Data quality	96	Yes	
5.3	Study valuation	100	Yes	
5.4	Cost allocation and compensation	103	Yes	
5.5	Further factors influencing cost sharing	105	Yes	
5.6	Cost sharing examples	107	Yes	
7	Information sharing under Competition rules	127	Partially	some aspects may be of relevance
8	Forms of Cooperation	132	Partially	some aspects may be of relevance
9	Confidential business Information (CBI)	140	Partially	some aspects may be of relevance

NB: the text of the Guidance on data sharing is to be read having the terminology of the BPR Regulation in mind:

REACH	BPR
Potential registrant	Prospective applicant
Previous/ existing registrant (within SIEF)	Data submitter/ owner
Registration	Application
Joint submission	N/A
Articles 27 and 30	Article 63
Article 26	Article 62
(Robust) study summaries	Tests and studies