Annex B. RPA analysis of the cost of testing and (Q)SARs based on data from the European Chemicals Agency's *Registration Database*

The European Chemicals Agency (ECHA) has undertaken analyses of new substances and existing substances registered under the REACH Regulation in the European Union to determine the extent to which the following have been used to fulfil information requirements for each (eco)toxicological endpoint:

- new experimental studies
- old experimental studies
- proposals for new experimental studies
- read-across
- (Quantitative) Structure-Activity Relationship [(Q)SAR]
- weight of evidence.

Data for the period up to March 2016 on the number of new and existing substances completing their data requirements via each of the above routes is described in the report entitled *The Use of Alternatives to Testing on Animals for the REACH Regulation* (ECHA, 2017).

Table B.1 provides a breakdown of the costs by endpoint. It also provides data on the average costs of new experimental studies drawn from the Risk & Policy Analysts Limited (RPA)'s in-house database of testing costs and the number of animals required to undertake tests.

Table B.1. **Endpoints, average costs of experimental studies and number of test animals required**

Endpoint	Number of animals required*	Average cost of experimental study (EUR)
Bioaccumulation	0	33 145
Short-term toxicity to fish	14	7 155
Long-term toxicity to fish	400	37 224
Long-term toxicity to birds	70	61 470
Toxicokinetics	60	1 300
Acute toxicity (all routes)	11	6 044
Skin irritation/corrosion	2	2 192
Eye irritation	2	1 647
Skin sensitisation	23	10 049
Repeated dose toxicity (all routes)	50	316 131
Genetic toxicity *in vitro*	0	11 402
Genetic toxicity *in vivo*	40	20 579
Carcinogenicity	400	1 210 128
Toxicity to reproduction	80	338 699
Developmental toxicity	100	112 191

* From Van der Jagt, K. et al. (2004).

These data have been used to derive estimates of the statistical average costs of new experimental studies and costs avoided owing to (Q)SARs via the OECD (Q)SAR Toolbox. These are provided in Table B.2.

For new industrial chemicals, costs are based on actual numbers of tests and (Q)SARs undertaken for new industrial chemicals registered in the EU and the average costs of experimental studies (as in Table B.1). In terms of costs avoided owing to (Q)SARs, it has been assumed that in the absence of a valid (Q)SAR or read-across, a new experimental study would be undertaken for all endpoints except the most expensive ones, namely repeated dose toxicity – all routes, carcinogenicity, toxicity to reproduction and developmental toxicity. For these endpoints it has been assumed that new experimental studies would only be carried out in 10% of cases where no (Q)SAR was available.

REACH requires different levels of information for substances manufactured or imported at different tonnages. As such, the level of information required for a given endpoint will differ from one tonnage to the next. Data from the European Chemical Agency's *Registration Database* (available at https://echa.europa.eu/information-on-chemicals/registered-substances) have been analysed to identify the number of substances requiring different levels (and costs) of individual tests (where they are required). These have been used to develop a statistical cost of new experimental studies and cost avoided by using (Q)SARs/read-across (employing the same assumptions above on the most expensive test endpoints in the absence of (Q)SARs/read-across).

Table B.2. **Average cost of testing for new and existing substances and savings owing to (Q)SARs**

	New substances	Existing substances
Average statistical cost of new experimental studies (EUR per substance)	169 531	80 740
Average statistical cost avoided via (Q)SARs/read-across (EUR per substance)[1]	20 545	30 162
Average cost per substance in the absence of (Q)SARs/read-across (EUR per substance)[2]	190 076	137 101
Average statistical test animals used (per substance)	76	46
Average statistical test animals avoided via (Q)SARs/read-across (per substance)	33	95

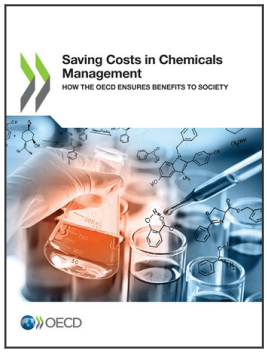
Notes:
1. These cost savings have been calculated on the assumption that in the absence of the OECD (Q)SAR Toolbox, experimental studies would otherwise need to be undertaken for all endpoints except the most expensive ones, namely repeated dose toxicity – all routes, carcinogenicity, toxicity to reproduction and developmental toxicity. For these endpoints it has been assumed that new experimental studies would only be carried out in 10% of cases where no (Q)SAR was available.
2. Costs for new substances are broadly comparable with the responses given on new substances in the 2018 EHS survey of industry (see Table A.2 in Annex A). The values in the table are used in the main analysis carried out by the RPA.

References

ECHA (2017), *The Use of Alternatives to Testing on Animals for the REACH Regulation*, Third report under Article 117(3) of the REACH Regulation, European Chemicals Agency, Helsinki, https://www.echa.europa.eu/documents/10162/13639/alternatives_test_animals_2017_en.pdf/075c690d-054c-693a-c921-f8cd8acbe9c3.

Van der Jagt, K. et al. (2004), "Alternative approaches can reduce the use of test animals under REACH", Addendum to the report "Assessment of additional testing needs under REACH: Effects of (Q)SARS, risk based testing and voluntary industry initiatives",

European Communities, Italy, http://publications.jrc.ec.europa.eu/repository/bitstream/JRC29111/EUR%2021405%20EN.pdf.



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