Table 15.4. Select models for predicting nano-biological interactions

Model	*Method*	*Purpose*	*Select Sources*
Quantitative Nano Property-Activity Relationship (QNAR)	Use of in vivo outputs to validate in vitro assays	Predictive relationship to estimate the effects of novel nanomaterials on biological organisms.	Meng et al. (2009), Burello and Worth (2010), and Puzyn et al. (2010)
Physiologically-based Pharmacokinetic (PBPK)	Combine physio-chemical and biochemical characteristics along with species-specific physiological properties	Study post-exposure absorption, distribution, metabolism and excretion (ADME) kinetics/dynamics of ENMs, predict biological interactions across a range of organisms, can support the development of derived no effect levels (DNELs) for RA	ECHA (2008), Riviere (2009), Lee et al. (2009), and Tran (2011)
Quantitative In Vitro-In Vivo Extrapolations (IVIVE) or Quantitative Property (in vivo) Property (in vitro) Relationship (QPPR)	Dose-response modeling of raw continuous, quantal or ordinal toxicity data	Correlates between in vitro and in vivo dose-response relationships. Assumes experimental results are standardized/ comparable, and the differences in data is only due to variations in the physio-chemical properties	Slob (2002), and Slob et al. (2008)

SOURCE: Data from Hristozov et al. (2012)

RA and LCA is still scarce. Two reviews provide critical insight into the need for more usable nano-EHS decision methods and data. Hristozov et al. (2012) and Grieger et al. (2010) reviewed ENMs in databases to determine data availability for ENMs. Hristozov et al. (2012) identified and compared seven open access databases that provide data for ENM assessment: nanoHub (Open Science), Hazardous Substances Data Bank (HSDB), Chemical Safety Database Searcher (CSDS), Stanford Chemical Safety Database (SCSD), Chemical Carcinogenesis Research Information System (CCRIS), Woodrow Wilson International Centre for Scholars (WWICS) Inventory of Consumer Products: WWICS Silver Nanotechnology Inventory. In their review, they found large discrepancies between the number of usable data sources for ENM RA and total number of data sources for six common ENMs. In addition, the authors demonstrate a shifting trend in nano-EHS data generation, as the majority of ongoing efforts are now focused on ENM exposure instead of (eco)toxicity.

Grieger et al. (2010) searched ISI Web of Knowledge and ICON bibliographic databanks for peer reviewed data on different nano-risk topics. The authors found the majority of publications present toxicity or ecotoxicity data, with limited risk assessment, management, governance, decision making or monitoring studies. While the need for usable (eco)toxicity data is important, the lack of studies that focus on decision making and governance, decision making, and monitoring will prevent use of the data as it is created. To address this gap, Grieger et al. 2010 recommend the reorientation of research priorities in nanotechnology to funds mores studies that produce adaptive and responsive risk governance frameworks, alternative tools to risk assessment (e.g., those detailed in section 2), and health and environmental surveillance programs. Improvements in these three research areas can save money and resources by avoiding lengthy, post-innovation investigations, accurate approximation of ENM risks, and early warning systems to provide a safety net to unforeseen risks.

15.5.3 Data Sources

In this section, brief descriptions of select online databanks and tools that provide nano-EHS data are presented.

The Nanomaterial Registry. The Nanomaterial Registry is developed by RTI International and is an authoritative and curated resource for nanomaterial physiochemical and biological interaction data. The registry acts as a centralized resource for nanomaterial data online, making older databases (i.e., the Nanotechnology Information Library) out of date. It is interactive, has regular updates, and presents several important pieces of information unavailable in other databases, such as guidelines for minimal information for physiochemical characteristics, biological, and environmental interactions and the ENM instance of characterization (i.e., sample preparation conditions and protocols). Furthermore, the registry has preliminary algorithms for sorting ENMs based on their similarity and analysis tools to compare two or more ENMs together.

The most important aspect of the Nanomaterial Registry is its curation process that includes a compliance rating for all data presented. Each data record is broken into physiochemical characteristics, environmental interactions, and biological interactions. Each characteristic is ranked on a 0–100 scale (low to high score) associated with four compliance levels (i.e., merit, bronze, silver, gold). Based on a weighted scale of 12 physiochemical characteristics, each piece of data is ranked, where higher values are given to records with the following qualities: high specificity, use of well-established measurement techniques, multiple measurement techniques, using standard protocols, and good laboratory practices. The use of the compliance rating is helpful for nano-EHS research, as it provides an immediate expert opinion on the efficacy of any data. Furthermore, it provides an efficient way to compare multiple records together, and determine if necessary data is missing from multiple records.

The cancer Nanotechnology Laboratory portal (caNanoLab). The caNanoLab is a tool meant to facilitate the sharing of ENM physiochemical and biological interaction data. The caNanoLab is developed by the National Cancer Institute, and provides access to important information regarding ENM sample data, protocols, and publications. In this respect, caNanoLab is an important resource for nano-EHS and RA professionals to not only collect relevant ENM data, but to learn state-of-the-art testing protocols that biomedical practitioners are using. In addition, the database has a secure submission system to expedite the validation of ENM biomedical research. In addition, caNanoLab is linked to other nanomaterial databases (i.e., The Nanomaterials Registry) to combine and bolster their individual datasets.

The International Council on Nanotechnology (ICON) database. Based out of Rice University, ICON is an organization focused on the development and communication of nano-EHS data. The ICON database is one the most thorough, nano-specific EHS databases available, and is designed to link search queries to nano-EHS publications (peer-reviewed or otherwise). Database records provide the record abstract alongside several important details useful for sorting nano-EHS data, including: content type, exposure or hazard target, exposure pathway, method of study (e.g., in vitro), paper type, particle type, production method, risk exposure group, and target audience. Using these details, ICON has a built in database analysis tool that facilitates quick comparisons of current nano-EHS data and reports.

The ICON database is linked with a number of other nano-EHS databases, sources and tools. In particular, ICON is linked to the OECD Database on Research into the safety of Manufactured Nanomaterials and the Nanoparticle Information Library.

NanoHub. NanoHub is an online repository for nanotechnology simulation tools, lectures and courses, and open access publications. It is a product of the Network for Computational Nanotechnology (NCN) based at Purdue University that links nanotechnology experts worldwide to share models and lectures. NanoHub is particularly useful for its ever expanding list of simulation tools (267 at the writing of this chapter) that are often cited in peer-reviewed publications and used by industry to assist in design. Although the majority of these tools are nonspecific for biophysical interactions or environmental fate and exposure, there are planned projects to bolster the current list with those that can model these situations. In addition, nanoHub is focused at improving general knowledge of nanotechnology, where its influential teaching modules, videos, and documents can be especially useful to any individual interested in conducting nano-EHS study.

InterNano. InterNano is tailored towards nanomanufacturing, and combines data with commentary to aggregate resources, reviews, and topical information on the current state of practice in the field. InterNano is a product of the National Nanomanufacturing Network (NNN) and is there virtual community for information sharing and data analysis. Although the intent of this source is for design in manufacturing, the data and commentaries have relevance for nano-EHS. Furthermore, InterNano utilizes its own taxonomy of nanomaterial terms to help organize its collection of articles, data, and sources. This makes it easy to find relevant publications associated with a specific nanomanufacturing situation and individuals from academia and industry associated who work in this field.

15.6 CONCLUSION

In this chapter we presented detailed descriptions of emerging RA methods, LCA for nanotechnology, RA frameworks that support governance, regulation, and risk screening, and current trends in data use. Although the RA methods presented herein are designed to provide near-term decisions on nanotechnology risks, the overarching theme that prevents successful RA is a lack of usable data. Because this deficit is predicted to persist, it is necessary that more models like those presented in section 2 and 4 be created and/or validated. Multi-criteria decision analysis and associated methods (i.e., WoE) and control and risk banding offer solutions to specific problems, but until they are properly validated, their efficacy remains in question. Moreover, the RA frameworks presented in section 4 each have identifiable strengths and weaknesses, while no single framework succeeds in all relevant ENM RA criteria (see Tables 15.2 and 15.3). For both models and frameworks, it would be beneficial to apply multiple methods to single ENM risk problem. This would allow the user to weigh the different results together and determine which framework is best at meeting the decision needs.

In addition, fundamental changes need to occur in LCA methods to support more efficient analysis and representation of ENM related risks. Some RA frameworks combine RA and LCA together to create a more comprehensive assessment. However, many of these frameworks are life cycle-based risk assessment, and fail to utilize LCA methodologies or provide important LCA benefits such as avoiding problem shifting (see section 3). Before combined LCA-RA frameworks will be able utilize both assessments together for decisions, there needs to be methodological developments in LCA. Moreover, the paucity of usable physiochemical and (eco)toxicological data and effective biological and environmental fate and exposure models puts serious restrictions on the ability of LCA to provide a usable result.

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