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A Survey of Environmental, Health and Safety Risk Management Information Needs and Practices among Nanotechnology Firms in the Massachusetts Region

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Preface

Spending on nanotechnology research and development by established corporations in North America hit $1.9 billion in 2005.[1] As time marches on, more and more companies—new and old, large and small—are capitalizing on the enhanced properties and new applications of materials and products enabled by nanotechnology, which is the ability to manipulate, observe and manufacture materials at the nanoscale, one billionth the size of a meter. Companies operating in almost every sector of the economy face challenges in understanding and addressing the possible adverse effects of these new nanoscale materials. How they address potential risks, with what methods and at what costs will have major impacts on their ability to commercialize nano-enabled products and processes over the next decade.

To better understand how nanotechnology firms (especially small and medium-size firms) are dealing with environmental, health and safety (EHS) management and what information they need to address risks proactively, our project helped support a study of New England-based nanotechnology firms

“We need rigorous taxonomy and metrology associated with defining materials so that (EHS management) risks can be understood, communicated, managed and regulated effectively.”

—Senior materials scientist from a small Massachusetts firm involved with nanotechnology process development

by researchers at the University of Massachusetts Lowell. Written by John Lindberg and Margaret Quinn, this paper presents the results of that study. New England was selected because the Northeast houses one of the greatest concentrations of companies, universities, government laboratories and organizations working in nanotechnology in the United States (see Figure P.1).

The survey, conducted by the authors of this paper, involved a two-step process: (1) an online survey of 180 managers of nanotechnology firms; and (2) in-depth interviews with 12 firms. One of the firms that agreed to the follow-up interview is located in Cambridge, Massachusetts, the second U.S. city to consider an ordinance for reporting on nanomaterial production, use and safety measures.

The survey produced two key findings: (1) nanotechnology firms recognize potential risks; however, (2) the firms (especially small firms) feel that they lack (a) information on the health and environmental risks of nanomaterials and (b) the necessary guidance from suppliers, industry, the government regulatory bodies and others in order to manage risks associated with materials and processes. These findings are consistent with those of other recent surveys of small and medium-size firms in Connecticut and New York[2] and of nano firms around the world.[3] The companies also indicated that they would prefer to receive nanomaterial EHS risk information from suppliers, professional/industry/trade associations (as mentors) and university technical assistance efforts and to access that information from web-based or electronic sources.

A recent front-page article in *The New York Times* bore the headline, “Without U.S. Rules, Biotech Food Lacks Investors.”[4] This survey’s findings suggest that many nano firms could face a similar fate. If we expect nanotechnology to deliver on its promise, innovative companies in the United States need not only clear guidance from government but also ready access to information on which to base sound business decisions concerning risk management. Much more effort needs to be expended to help businesses succeed as they bring innovative nanotech products to market.

—David Rejeski
Director, Project on Emerging Nanotechnologies

Figure P.1: Concentration of Nano Firms, Universities, Government Laboratories and Other Organizations across the Continental United States

ABOUT THE AUTHORS

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“I need (EHS risk management) information so that I can work with our VP of Quality in preparing responses to anticipated customer inquiries about nanotechnology content when we bring our products to market…”
—Director of technology for a large Massachusetts manufacturer

EXECUTIVE SUMMARY

Massachusetts ranks as one of the top U.S. states for investment in nanotechnology research and commercialization.[5] This survey of a sample of nanotechnology firms in Massachusetts and adjoining areas of New England was conducted to evaluate environmental, health and safety (EHS) risk management information needs and practices among these firms. The results of this survey are intended to provide a base for the development of government policies for nanotechnology EHS risk management and to inform the development of academic programs and workplace training to address EHS needs in nanotechnology industries. For this survey, EHS risk management was defined as “a systematic approach to identifying and managing areas of employee occupational health, workplace safety and environmental impact beyond the firm.”

Overall, the findings indicate recognition of potential EHS risk from nanoscale particles and associated process hazards, especially in larger firms. However, the ability to manage the risk is limited by a lack of information on the health and environmental impacts of nanotechnology and on how to control them.

Other key findings include:

Larger firms most often indicated that they were currently taking steps to manage nanotechnology EHS risk and that they believe there is risk associated with their materials and processes. In contrast, the smaller firms most often indicated they were not taking steps to manage risk and they did not recognize the presence of risk in their materials and processes.

The most frequently mentioned barrier to understanding and managing EHS risks associated with nanotechnology was “insufficient information available to quantify risk” (50% of responses). Material and staff resources were not obstacles to managing risk for large firms but were an obstacle for smaller firms that recognized risk and were attempting to manage it.

In general, firms that were taking steps to manage risk were relying on existing supplier data (material safety data sheets [MSDS], which are mandatory for produced and sold materials), expert judgment, best practices or current regulatory requirements as guidelines. There is very limited product documentation in the form of MSDS or product safety guidelines that specifically identify nanotechnology content or related EHS risk. Survey respondents indicated the importance of ease of access to EHS risk information (e.g., MSDS from material suppliers) and a preference for accessing that information through the Internet. A majority of the participants indicated that they believed their firm would benefit from working with a university on EHS risk management issues.

WEB-BASED SURVEY RESULTS

This survey consisted of an initial web-based questionnaire administered via e-mail to 180 managers in nanotechnology firms. It was followed by a more in-depth questionnaire administered by telephone interview to a subset of the initial survey recipients who agreed to participate in the follow-up. The response rate for the initial web-based questionnaire was 24% (43 firms participating) with 12 firms consenting to the follow-up interviews. The results from the web-based survey are presented below, and interview results follow. Further details on the methodology are provided in the appendix.

Demographic Characteristics of Participants

Initial respondents were distributed as follows:

- Firm size: 30% micro (fewer than 10 employees), 21% small (10–99 employees), 19% medium (100–499 employees) and 30% large (500 or more employees).
- Stage of the nanotechnology venture: 21% at start-up, 56% at research & development (R&D) and 23% at full commercialization.
- Distribution of size within stage of venture:
  - At start-up: 50% micro, 25% small and 25% medium.
  - At R&D: 25% micro, 10% small, 25% medium and 40% large.
  - At full commercialization: 38% micro, 25% small, 12% medium and 25% large.
- The industrial sectors represented included automation, biotechnology, chemicals, consumer products, defense/aerospace, energy, materials, manufacturing, medical devices, pharmaceuticals, photonics, subassembly, telecommunications, test and measurement and intellectual property/consulting with a broad range of products and/or services.
- Initial survey respondents were not asked to identify their specific position within the firm, although the list of e-mails was known to be built from among those who participated in exchanges with universities, regional economic development organizations and the media.

Managing EHS Risk

In general, firms that were taking steps to manage risk were relying on existing supplier data, expert judgment, best practices or current regulatory requirements as guidelines.

When firms were asked whether they were currently taking steps to manage EHS risk associated with nanotechnology, 53% responded "yes," 39% responded "no" and 8% were "not sure." The **size of the firm** significantly influenced the distribution of response to this question, with 80% of large firms, 63% of medium firms, 33% of small firms and 33% of micro firms responding "yes." The **stage of development** of the nanotechnology venture also appeared to influence the distribution of responses to this question, with nanotechnology ventures at start-up answering 12% "yes," 75% "no" and 12% "not sure." Nanotechnology ventures at R&D answered 70% "yes," 25% "no" and 5% "not sure." Nanotechnology ventures at full commercialization answered 50% "yes," 37% "no" and 12% "not sure." Figure 1 summarizes

Figure 1: Percentage of Firm Types Taking Steps to Manage Nanotechnology EHS Risk

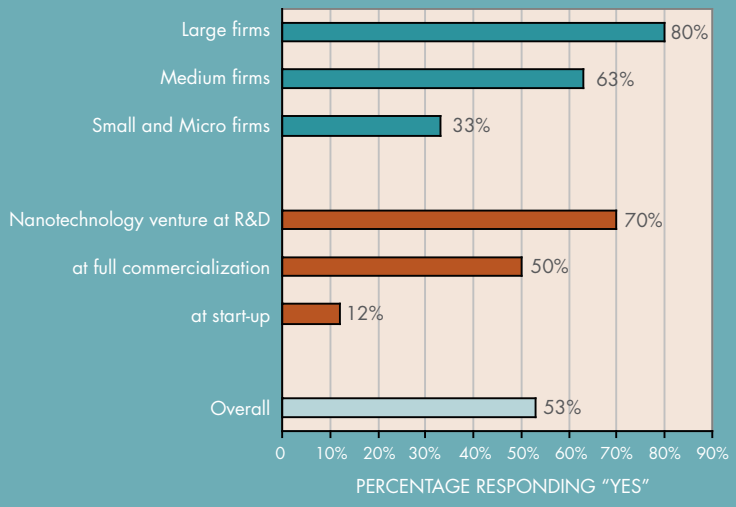

Table 1: Barriers to Managing Nanotechnology EHS Risk by Firm Size

Barriers	Percentage Response by Category				
	Micro Firms	Small Firms	Medium Firms	Large Firms	All Responses
Lack of sufficient information to quantify risk	33%	33%	63%	70%	**50%**
Lack of sufficient time or personnel to address the matter	17%	0%	25%	0%	**11%**
Lack of financial resources to address the matter	17%	0%	25%	0%	**11%**
Do not currently face barriers to managing risk	17%	33%	13%	30%	**22%**
Do not believe there is EHS risk associated with processes or materials	42%	83%	25%	0%	**33%**

Note: Columns may not total to 100% because multiple responses were possible.

these results. Those firms answering "yes" to this question provided descriptions of steps being taken to manage EHS risks. Summarized in general terms, these steps included reliance on supplier material safety data sheets (MSDS), reliance on best industry practices, reliance on expert staff or consultants and adherence to existing regulatory requirements governing occupational safety and environmental compliance.

Barriers to EHS Risk Management

When asked to select all applicable choices from five categories of barriers to understanding and managing EHS risks associated with nanotechnology, participants most frequently selected the "insufficient information available to quantify risk" category (50% of responses).

The remaining categories and the percentages of responses included "insufficient time or personnel to address the matter" (11%), "insufficient financial resources to obtain assistance" (11%), "do not currently face barriers to managing EHS risk" (22%) and "do not believe there is EHS risk associated with our processes or materials" (33%). With respect to the size of the firm in the distribution of responses to the question of barriers to risk management, the large firms indicated that they either lacked sufficient information to quantify risk (70%) or that they did not face barriers to managing risk (30%). No large firms indicated lack of staff, time or financial resources to address the matter. Additionally, no large firms indicated an absence of EHS risk associated with their processes or materials. Micro, small and medium-size firms also identified lack of sufficient information to quantify risk as a barrier at 33%, 33% and 63%, respectively, within each category. The micro and medium-size firms also identified lack of staff, time and financial resources as barriers to understanding and managing EHS risk associated with nanotechnology at 17% and 25% of respondents, respectively, within each category. There were also micro, small and medium-size firms that indicated no barriers to managing EHS risk (17%, 33% and 13% of respondents, respectively, within each category).

In contrast to the responses of large firms were micro, small and medium-size firms that indicated a belief that there was no EHS risk associated with their materials or processes (42%, 83% and 25%, respectively). Table 1 summarizes these results.

Stage of development of the nanotechnology venture presented more mixed responses with no evident trends other than the pattern of selecting insufficient information available to quantify risk (75% at start-up, 50% at R&D and 25% at full commercialization).

"Our efforts to commercialize this technology would benefit from (EHS risk management) information generated by universities and government."

—Associate principal in a medium-size Massachusetts technology development firm

Information Preferences

Ease of access to EHS risk information through the Internet in the familiar form of an MSDS from material suppliers was the most highly ranked preference for obtaining information by survey respondents.

Respondents to the initial web-based questionnaire were asked to rank-order preferred methods for obtaining information on nanotechnology EHS risk management from among five choices: printed material, electronic media, Internet site, on-site presentation and off-site presentation. Their preferences were:

1. Internet site;
2. Electronic media (for example, compact discs);
3. Printed material;
4. On-site presentations; and
5. Off-site presentations.

Respondents were also asked to rank the preferred source of information from among the following six options: government agency, university technical assistance, public interest group, professional/industry/trade association, consulting/law firm or material supplier. Respondents' preferences took the following order:

1. Material supplier (MSDS);
2. Professional/industry/trade association;
3. University technical assistance;
4. Government agency;
5. Public interest group; and
6. Consulting/law firm.

FOLLOW-UP INTERVIEW RESULTS

Demographic Characteristics of Participants

The 12 participants in the follow-up interviews offered greater insight into how nanotechnology firms in the Massachusetts region are managing EHS risk and what additional information or technical assistance would benefit their efforts.

- Firm size: 33% micro, 8.5% small, 8.5% medium and 50% large.
- Stage of the nanotechnology venture: 50% at R&D and 50% at full commercialization.
- The 12 participants were asked to identify the position they held in their nanotechnology firm. More than half were founders or principals in their firms; 11 were at the senior or executive management level and eight held doctoral degrees in science or engineering.
- Geographically, the 12 participants represented firms with locations in Massachusetts (9), New Hampshire (2) and Rhode Island (1).
- These firms were representative of energy technology, electronic manufacturing services, organic- and inorganic-particle manufacturing, compounded polyvinyl chloride and colorant manufacturing, precision injection molding, plasma deposition and etching, microscopy, technology innovation and investment, defense electronics, aerospace and electronics, surface coatings and pharmaceutical synthesis and discovery technology.

Supply Chain

The diversity of the supply chain relationships and activities in developing commercial applications of nanotechnologies was evident from the range of supply chain positions (nodes) and opportunities for interactions among the participants in the follow-up interviews.

When asked where in the supply chain, beginning with the creation of raw materials and leading to anticipated end-use, the firm's nanotechnology product or service appeared, one participant described material synthesis at the start of the supply chain, seven described processing at the midsupply chain, three described end-use points and one chose not to disclose for reasons of intellectual property protection. When asked where in the supply chain leading to their product or service nanoscale materials (that is, materials with one dimension or more at less than 100 nanometers [nm]) appear, eight participants indicated that materials came from suppliers, two indicated that the materials were created in their process, one indicated that the materials were created at end use point and one chose not to disclose for reasons of intellectual property protection. When asked whether the work of their firm involved handling nanoscale particles, nine participants indicated "yes" (two of these respondents indicated that the particles are in solution and one indicated that some of the particles could be larger than the 100-nm dimension) and three indicated "no." Participants were also asked whether there was any fabrication with materials containing nanoscale particles within their firm (involving activities such as milling, cutting, welding, spraying or grinding). Answers to this question were four "yes," six "no" and two "not yet."

The diversity of the supply chain relationships and activities in developing commercial applications

of nanotechnologies is illustrated in Figure 2 for the relatively small sample of firms that participated in the follow-up interviews. The majority of the nanotechnology products or services occur at or prior to the middle of the path leading to the anticipated end-use. Between these points and the anticipated end-use, there exists the potential for multiple nodes engaged in multiple processing steps and yet further branching. Prior to the value-added activity of the participating firms, there is supply node processing and potential branching for eight of the 12 respondents.

EHS Risk Management Practices

Responses indicated a reliance on existing control systems, protective equipment, employee training and environmental operating practices, as well as EHS staff judgment, to manage EHS risk during the introduction of nanotechnology.

Participants were asked a series of questions on their firms' current EHS risk management practices. The questions and a representation of responses are presented in Table 2. In the traditional model of managing workplace hazards, it is preferable to survey pathways to exposure before developing a strategy of controls, protective equipment use and employee training. Responses of participants in this survey indicated, however, that the assignment of controls and protective equipment has preceded the assessment of exposure risk for more than half of the firms interviewed. This can reasonably be considered a result of insufficient nanotechnology-specific information to complete the exposure assessment and therefore a necessary reliance on existing control systems and protective equipment. It is reasonable to infer from the responses to the question relating to transport, storage and disposal procedure development that the ability to create standard operating practices for managing potential environmental impact beyond the firm is also limited by a lack of nanotechnology-specific information and regulatory guidance. Firms with professional EHS staff are relying on the best judgment of these individuals to bridge the information gap both within and beyond the workplace.

"At this time we don't understand what regulatory requirements may be uniquely applicable to nanotechnology and nanoparticles."

—Senior safety manager for a large manufacturing and technology corporation based in Massachusetts

Figure 2

Location of Nanotechnology Survey Participants' Products or Services Along the Supply Chain Leading to Anticipated End-Use

Start (1) → **Middle (7)** → **End-Use (3)**

Origin of Nanoscale Materials:

- Supplier (8)
- At process within firm (2)
- At end-use (1)

Activity within the Firm:

- Handling nanoparticles? Y (9), N (3)
- Fabricating with materials containing nanoparticles? Y (4), N (6), Not yet (2)

Table 2: EHS Risk Management Practices in Participating Nanotechnology Firms

Question	Number Responding			
	Yes	Yes (but not nanospecific)	No	Not Sure
Does your firm have an **EHS staff?**	8	Not applicable	4	0
Has your firm developed procedures for **employee exposure assessment** to nanoscale particles and associated process hazards?	5	0	7	0
Does your firm employ **process controls to reduce exposure** to nanoscale particles and associated process hazards?	7	4	1	0
Does your firm require employees to **use personal protective equipment** to reduce exposure to nanoscale particles and associated process hazards?	5	6	1	0
Does your firm provide specific **employee training** regarding risk of exposure to nanoscale particles and associated process hazards?	3	4	4	1
Has your firm developed procedures for **transport, storage and disposal** of nanoscale particles?	2	1	9	1

Product Documentation

Based on the responses, there is very limited product documentation in the form of MSDS or product safety guidelines that specifically identify nanotechnology content or related EHS risk.

Participants were asked whether they were producing a MSDS for nanoscale particles or products that contain such particles. Only one participant indicated that an MSDS was produced for a material containing nanoscale particles; however, it was unclear at the time of the interview whether there was specific mention of the presence of nanoscale particles in the MSDS. Participants were then asked whether their firm produced product safety documentation specifically mentioning nanoscale particles for users of products that contain such particles. None of the participants indicated that they were aware of such documentation being produced by their firms. A number of respondents indicated the intention to produce MSDS and product safety documentation at an appropriate time in the future depending on the progress of the nanotechnology venture and the specific requirements that appeared applicable.

EHS Management Systems

Where EHS management systems have been implemented among survey participants, only one firm had distinctly incorporated nanotechnology-specific language in its EHS policy.

Current implementation of EHS management systems constituted the next section of the follow-up questionnaire. The questions and a summary of responses to the questions are presented in Table 3. The questions reflect a subset of the hierarchical planning elements in the structure of an International

“Nanotechnology needs a credible voice for communicating (EHS) risk to consumers and the general public; that need can be supported by university research.”

—Scientist in a small Massachusetts technology firm

Organization for Standardization (ISO)-style environmental management system wherein an organization establishes a policy around which the system is structured to meet key stakeholder requirements. These results indicate that the majority of responding firms do not have EHS management systems. Firms that have established EHS policies typically do not include nanotechnology-specific EHS risk management guidance. The majority of responding firms also indicated that they have not fully identified applicable regulatory and other key stakeholder requirements for the handling, storage, transport, disposal and sale of nanoscale particles or materials that contain such particles.

Role of the University

At three points in the follow-up interviews (*EHS risk management practices, product documentation and EHS management systems*), participants were asked whether their firm would benefit from university-based technical assistance with developing capabilities for managing EHS risk associated with their nanotechnology venture. At each of these points in the follow-up interviews 50–75% of the participants indicated that they believed their firm would benefit from such a relationship if the opportunity became available.

Table 3: EHS Management Systems of Participating Nanotechnology Firms

Question	Number Responding		
	Yes	No	Not Sure
Does your firm implement an **EHS management system?**	5	4	3
Does your firm have an **EHS policy**?	7	5	0
Has your firm identified applicable regulatory and other (customer, stakeholder) **requirements for handling, storage, transport, disposal and sale** of nanoscale particles or materials that contain nanoscale particles?	4	7	1
Among the seven firms with an EHS policy:			
Is the **policy available to customers** and other interested stakeholders?	5	2	0
Does the **policy incorporate guidance for nanotechnology or nanoscale particles**?	1	6	0

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SUMMARY

The strategy of employing an initial, brief web-based questionnaire followed by a more in-depth interview proved successful in that the survey sample was broad in terms of firm size and stage of the nanotechnology venture, as well as of industrial sector represented. It was also an efficient method for conducting the survey given the limited resources available. Insight into the degree to which nanotechnology and nanoscale particles are beginning to enter the manufacturing supply chain is represented in the diversity of industrial sector, stage of development and participant responses to questions regarding point of supply chain introduction.

Overall, the findings indicate recognition of potential EHS risk associated with nanoscale particles and associated process hazards; however, the ability to manage risk is limited by lack of information with which to quantify and evaluate risk. The survey results also revealed the following:

Larger firms most often indicate that they believe there is EHS risk associated with their materials and processes and are currently taking steps to manage it. Smaller firms, by contrast, often did not recognize the presence of risk in their materials and processes and therefore were not taking steps to manage it.

Material and staff resources were not an obstacle to managing risk for large firms but were an obstacle for smaller firms that recognized risk and were attempting to manage it.

In general, firms that were taking steps to manage risk were relying on existing supplier data (MSDS), expert judgment, best practices or current regulatory requirements as guidelines. Preferred methods of obtaining EHS risk management information were, in rank order, the Internet, electronic media, printed material, on-site presentations and off-site presentations. Preferred sources of information were, in rank order, suppliers (MSDS), professional/industry/trade association, universities, government agencies, public interest groups and consulting/law firms.

The desire for ready access to EHS risk information through familiar means points to the importance of sufficient funding of research to enable suppliers and others to present reliable information based on properties of nanoscale materials rather than on assumptions of properties using chemical composition and biological activity at lower surface/mass ratios.

With limited regulatory guidance for managing EHS risk associated with nanoscale particles, even firms that are producing MSDS or other product safety documentation for these materials lack points of reference within which to develop a framework for interpreting risk.

Current use of EHS management systems approaches among the survey participants indicates that even where such systems have been deployed, nanotechnology-associated risks are not distinguished in policy statements, and regulatory, customer and other stakeholder requirements have not yet been fully identified.

The results of this survey offer insight on the current state of EHS risk management in the nanotechnology private sector in and around the Massachusetts area. These results are significant in the context of the larger national concerns for EHS risk management needs in that the sample population is from a region that is ranked as a leader in nanotechnology research and commercialization. These findings are also generally supportive of results from a global survey of nanotechnology EHS practices commissioned by the International Council on Nanotechnology and published in November 2006.[6]

APPENDIX: METHODOLOGY

The majority of the firms targeted for survey distribution were identified with assistance from National Science Foundation's Nanoscale Science and Engineering Center (Center for High-Rate Nanomanufacturing) and member universities, the University of Massachusetts Lowell and Northeastern University, as well as the Massachusetts Technology Collaborative's Nanotechnology Initiative and the Project on Emerging Nanotechnologies. The survey consisted of an initial web-based questionnaire administered via e-mail to 180 managers in nanotechnology firms in Massachusetts and adjoining areas of New England. It was followed by a more in-depth questionnaire administered by telephone interview to a subset of the initial survey recipients who agreed to participate in the follow-up.

The initial questionnaire was distributed in February 2007, and the follow-up interviews were performed in March and April 2007. The initial 12-question instrument was developed for this survey to obtain basic demographic information on each firm (number of employees, sector, stage of nanotechnology venture development, product or service) as well as current actions being taken to manage EHS risk associated with the commercialization of nanotechnologies, barriers to understanding and managing this risk and preferences for sources and methods of receiving information on nanotechnology EHS risk management. Time to complete the web-based questionnaire was estimated to be less than 10 minutes. The follow-up interview questionnaire required 20–30 minutes to administer and contained 28 questions organized into four sections:

(a) basic description of the firm, including point of emergence of nanotechnology in the supply chain;
(b) handling and processing of nanoscale particles;
(c) risk management, including hazard assessment, use of controls, personal protective equipment and training, transport, storage, disposal, authorship of MSDS and product safety documentation; and
(d) management systems implementation.

NOTES

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6. See *supra* note 3.

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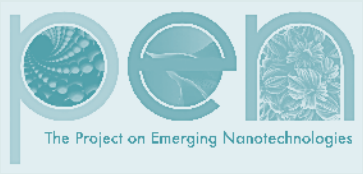

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