

A Free Software for Food Industries to Ensure Food Safety: CARVER + Shock

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Abstract: Bio-terrorism is not a new term for scientists. Post 9/11 the United States of America, as well as other countries which have grown well economically and countries undergoing the metamorphosis to developed nations, are under serious threat of bio-terrorism. This has led to the development of the software CARVER + Shock by Sandia National Laboratories and Food and Drug Administration (FDA), specifically for risk assessment and protection mechanism in the entire food supply chain from farm to table. This software requires training on the software front and interaction with industry people to chalk out a plan to safeguard the premises and the supply chain of the food products in the industry manufacturing. Such efforts should be well highlighted and advertised among food processing professionals, educators, students, and those government agencies concerning the food safety issues. Everyone must look at this software as this is going to be the future of food processing safety. This system works like Hazard Analysis and Critical Control Points and can be integrated for total quality management of the concerned industry. Our study has highlighted the application of this software in various food industries showing its strength and weaknesses.

Introduction

Food safety concerns used to focus solely on accidental contamination. But in recent years, there has been concern that terrorists could intentionally introduce biological, chemical, or radiological agents. A risk assessment tool called CARVER + Shock helps food processors protect their products from deliberate contamination (Acheson 2007b).

CARVER was originally developed by the U.S. military to identify areas that may be vulnerable to an attacker. Food and Drug Administration (FDA) and other agencies have used the method to evaluate potential vulnerabilities in the supply chains of different foods and food processes (Pohl 2007).

The CARVER + Shock method is an offensive targeting prioritization tool that has been adapted for use in the food sector. This tool can be used to assess the vulnerabilities within a system or infrastructure to an attack. It allows you to think like an attacker by identifying the most attractive targets for attack. By conducting such a vulnerability assessment and determining the most vulnerable points in your infrastructure, you can then focus your resources on protecting your most vulnerable points (News 2007).

CARVER is an acronym for the following 6 attributes used to evaluate the attractiveness of a target for attack:

- **Criticality**—measure of public health and economic impacts of an attack.

- **Accessibility**—ability to physically access and egress from target.
- **Recuperability**—ability of system to recover from an attack.
- **Vulnerability**—ease of accomplishing attack.
- **Effect**—amount of direct loss from an attack as measured by loss in production.
- **Recognizability**—ease of identifying target.

A 7th attribute, **Shock**, has been added to the original 6 to assess the combined health, economic, and psychological impacts of an attack within the food industry (USFDA 2005).

Computerizing CARVER

CARVER has traditionally been used in a face-to-face setting. Experts from FDA and/or U.S. Dept. of Agriculture have gone to food processing plants and held meetings. The software program takes companies through more than 100 questions about their facilities and processes to help them identify vulnerable areas (USFDA 2007c).

Companies consider what type of attack is the greatest threat and whether a biological or chemical agent might be used in an attack. The questions center around which food supply chain the company will assess, whether pizza production or a generic process from farm to table (USFDA 2007a, 2007c).

Material and Methods

The attractiveness of a target can then be ranked on a scale from 1 to 10 on the basis of scales that have been developed for each of the 7 attributes.

Conditions that are associated with lower attractiveness (or lower vulnerability) are assigned lower values (1 or 2), whereas

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Table 1—Criticality.

Criticality: A target is critical when introduction of threat agents into food at this location would have significant health or economic impact. Example metrics are:	
Criticality Criteria —Use this scale to assess: An individual food processing facility	Scale
Loss of over 10,000 lives OR loss of > 90% of the total economic value.	9-10
Loss of life is between 1,000-10,000 OR loss of between 61% and 90% of the total economic value.	7-8
Loss of life is between 100 and 1000 OR loss of between 31% and 60% of the total economic value.	5-6
Loss of life is less than 100 OR loss of between 10% and 30% of the total economic value.	3-4
No loss of life OR < 10% of the total economic value.	1-2
Criticality Criteria —Use this scale to assess: An individual crop or animal agriculture facility	Scale
Loss of > 90% of animal lives or total economic value.	9-10
Loss of 61% - 90% of animal lives or total economic value.	7-8
Loss of 31% - 60% of animal lives or total economic value.	5-6
Loss of 10% - 30% of animal lives or total economic value.	3-4
Loss < 10% of animal lives or total economic value.	1-2

conditions associated with higher attractiveness as a target (or higher vulnerability) are assigned higher values (9 or 10). Evaluating or scoring the various elements of the food sector infrastructure of interest for each of the CARVER + Shock attributes can help identify where within that infrastructure an attack is most likely to occur (USFDA 2007a).

Federal agencies, such as the Food Safety and Inspection Service (FSIS) and the FDA, have used this method to evaluate the potential vulnerabilities of farm-to-table supply chains of various food commodities. The method can also be used to assess the potential vulnerabilities of individual facilities or processes (Acheson 2007a).

Steps for conducting a CARVER + Shock analysis

Step 1—establishing parameters. Before any scoring can begin, the scenarios and assumptions you wish to use in the analysis must be established in order to guide all further steps. That is, you need to answer the question of what you are trying to protect and what you are trying to protect it from. Those parameters include:

- What food supply chain you are going to assess (hot dog production or deli meat production or chicken nugget production, an overall assessment based on the generic process from farm to table or postslaughter processing in a specific facility and so on.);

- What is the endpoint of concern (food borne illness and death or economic impacts and so on.);
- What type of attacker and attack you are trying to protect against. Attackers could range from disgruntled employees to international terrorist organizations. Those different attackers have different capabilities and different goals. For example, a major assumption used by FSIS and FDA in their vulnerability assessments is that one of the goals of terrorist organizations is to cause mass mortality by adding acutely toxic agents to food products. That assumption has a major impact on the scoring of the various parts of the supply chain and the scales for the attributes (see below) have been developed with that in mind;
- What agent(s) might be used? The agent used in your scenario will impact the outcome of the assessment. Potential agents include biological, chemical, or radiological agents. Different agents have different properties such as potency, heat stability, pH stability, half-life that will determine the impact of an intentional contamination incident (USFDA 2007a).

Step 2—assembling experts. A team of subject matter experts should be constituted to conduct the assessment. The team should consist, at a minimum, of experts in food production (specifically for the food process being evaluated), food science, toxicology,

Table 2–Accessibility.

Accessibility: A target is accessible when an attacker can reach the target to conduct the attack and egress the target undetected. Accessibility is the openness of the target to the threat. This measure is independent of the probability of successful introduction of threat agents. Example metrics are:	
Accessibility Criteria	Scale
Easily Accessible (e.g., target is outside building and no perimeter defense). Limited physical or human barriers or observation. Attacker has relatively unlimited access to the target. Attack can be carried out using medium or large volumes of contaminant without undue concern of detection. Multiple sources of information concerning the facility and the target are easily available.	9-10
Accessible (e.g., target is inside building, but in unsecured part of facility). Human observation and physical barriers limited. Attacker has access to the target for an hour or less. Attack can be carried out with moderate to large volumes of contaminant, but requires the use of stealth. Only limited specific information is available on the facility and the target.	7-8
Partially Accessible (e.g., inside building, but in a relatively unsecured, but busy part of facility). Under constant possible human observation. Some physical barriers may be present. Contaminant must be disguised, and time limitations are significant. Only general, non-specific information is available on the facility and the target.	5-6
Hardly Accessible (e.g., inside building in a secured part of facility). Human observation and physical barriers with an established means of detection. Access generally restricted to operators or authorized persons. Contaminant must be disguised and time limitations are extreme. Limited general information available on the facility and the target.	3-4
Not Accessible. Physical barriers, alarms, and human observation. Defined means of intervention in place. Attacker can access target for less than 5 minutes with all equipment carried in pockets. No useful publicly available information concerning the target.	1-2

epidemiology, microbiology, medicine (human and veterinarian), radiology, and risk assessment. The team will apply the CARVER + Shock method to each element of food system infrastructure and come to a consensus on the value from 1 to 10 for each attribute, using the scenario and assumptions established in Step 1 (Rigby 2006; USFDA 2007b).

Step 3—detailing food supply chain. The analysis begins by developing a description of the system under evaluation.

A graphical representation (flow chart) of the system and its subsystems, complexes, components, and nodes (its smaller structural parts) should be developed to facilitate this process. For example, if you are evaluating hot dog production, the food system is hot dog production that can be broken down into subsystems (production of live animals subsystem, slaughter/processing subsystem, distribution subsystem). Those subsystems can be further broken down into complexes (such as slaughterhouse facility and processing facility) Those can be broken down into components and would

include the raw materials receiving area, processing area, storage area, shipping area, and so on), and to the smallest possible nodes (for example, individual pieces of equipment) (FDA 2007; News 2007; Pohl 2007).

Step 4—assigning scores. Once the infrastructure has been broken down into its smallest parts (components and nodes), these can be ranked or scored for each of the 7 CARVER + Shock attributes to calculate an overall score for that node. The nodes with the higher overall scores are those that are potentially the most vulnerable nodes (and, therefore, most attractive targets for an attacker). The rationale for a particular consensus score should be captured (Donald Kautter 2006; Danneels 2007).

Step 5—applying what has been learned. Once the critical nodes of the system have been identified, a plan should be developed to put countermeasures in place that minimize the attractiveness of the nodes as targets. Countermeasures might include enhancements to physical security, personnel security, and

Table 3–Recuperability.

Recuperability: A target's recuperability is measured in the time it will take for the specific facility to recover productivity. Example metrics are:	
Recuperability Criteria	Scale
> 1 year	9-10
6 months to 1 year	7-8
3-6 months	5-6
1-3 months	3-4
< 1 month	1-2

Table 4–Vulnerability.

Vulnerability: A measure of the ease with which threat agents can be introduced in quantities sufficient to achieve the attacker's purpose once the target has been reached. Vulnerability is determined both by the characteristics of the target (e.g., ease of introducing agents, ability to uniformly mix agents into target) and the characteristics of the surrounding environment (ability to work unobserved, time available for introduction of agents). It is also important to consider what interventions are already in place that might thwart an attack. Example metrics are:	
Vulnerability Criteria	Scale
Target characteristics allow for easy introduction of sufficient agents to achieve aim.	9-10
Target characteristics almost always allow for introduction of sufficient agents to achieve aim.	7-8
Target characteristics allow 30 to 60% probability that sufficient agents can be added to achieve aim.	5-6
Target characteristics allow moderate probability (10 to 30%) that sufficient agents can be added to achieve aim.	3-4
Target characteristics allow low probability (less than 10%) sufficient agents can be added to achieve aim.	1-2

Table 5–Effect.

Effect: Effect is a measure of the percentage of system productivity damaged by an attack at a single facility. Thus, effect is inversely related to the total number of facilities producing the same product. Example metrics are:	
Effect Criteria	Scale
Greater than 50% of the system's production impacted	9-10
25-50% of the system's production impacted	7-8
10-25% of the system's production impacted	5-6
1-10% of the system's production impacted	3-4
Less than 1% of system's production impacted	1-2

Table 6–Recognizability.

Recognizability: A target's recognizability is the degree to which it can be identified by an attacker without confusion with other targets or components. Example metrics are:	
Recognizability	Scale
The target is clearly recognizable and requires little or no training for recognition	9-10
The target is easily recognizable and requires only a small amount of training for recognition	7-8
The target is difficult to recognize or might be confused with other targets or target components and requires some training for recognition	5-6
The target is difficult to recognize. It is easily confused with other targets or components and requires extensive training for recognition	3-4
The target cannot be recognized under any conditions, except by experts.	1-2

Table 7–Shock.

Shock: Shock is the final attribute considered in the methodology. Shock is the combined measure of the health, psychological, and collateral national economic impacts of a successful attack on the target system. Shock is considered on a national level. The psychological impact will be increased if there are a large number of deaths or the target has historical, cultural, religious or other symbolic significance. Mass casualties are not required to achieve widespread economic loss or psychological damage. Collateral economic damage includes such items as decreased national economic activity, increased unemployment in collateral industries, etc. Psychological impact will be increased if victims are members of sensitive subpopulations such as children or the elderly.	
Shock	Scale
Target has major historical, cultural, religious, or other symbolic importance. Loss of over 10,000 lives. Major impact on sensitive subpopulations, e.g., children or elderly. National economic impact more than \$100 billion.	9-10
Target has high historical, cultural, religious, or other symbolic importance. Loss of between 1,000 and 10,000 lives. Significant impact on sensitive subpopulations, e.g., children or elderly. National economic impact between \$10 and \$100 billion.	7-8
Target has moderate historical, cultural, religious, or other symbolic importance. Loss of life between 100 and 1,000. Moderate impact on sensitive subpopulations, e.g., children or elderly. National economic impact between \$1 and \$10 billion.	5-6
Target has little historical, cultural, religious, or other symbolic importance. Loss of life less than 100. Small impact on sensitive subpopulations, e.g., children or elderly. National economic impact between \$100 million and \$1 billion.	3-4
Target has no historical, cultural, religious, or other symbolic importance. Loss of life less than 10. No impact on sensitive subpopulations, e.g., children or elderly. National economic impact less than \$100 million.	1-2

operational security that help to minimize aggressor access to the product or process (Catlin and Kautter 2007).

Description of attributes and scales

The following section defines the attributes used by FDA and USDA to conduct their vulnerability assessments and provides the scales used by the agencies for scoring each attribute. These scales were developed with the mindset that mass mortality is a goal of terrorist organizations. It is important to remember, however, that any intentional food contamination could also have major psychological and economic impacts on the affected industry. Tables to assist in calculating the public health impacts and the overall CARVER + Shock scores can be found in Table 8 and 9, respectively (USFDA 2005; News 2007).

CARVER + Shock scoring table (individual facilities). See Table 1 to Table 7.

Criticality of the attack

This table can be used to calculate the potential number of deaths and illnesses resulting from addition of a particular adulterant at a particular point in a given food production process. Details of the batch size to which the adulterant is added, the number of servings that will be sold and eaten from that batch, and the characteristics of the adulterant (including its lethality) must be known to use this worksheet. The numbers generated in this worksheet will help determine where on the criticality scale a given attack will fall (see table 8).

Summary sheet for total scores. This table can be used to total the scores across the CARVER + Shock attributes for each node. The totals can then be compared across the various nodes to determine which nodes are critical. The nodes with the highest scores are the “critical nodes” and should be the focus for beginning to implement countermeasures (see table 9).

Software Installation and Startup

The software CARVER + Shock is copyrighted by Sandia National Laboratories and FDA. Its version 1.0.0.0 is available for usage for free.

CARVER + Shock runs on hardware systems with the following minimum performance characteristics:

- (1) Pentium I processor
- (2) 256 MB RAM
- (3) 120 MB available hard disk space
- (4) CD ROM drive
- (5) Video card displaying 1280 × 1024 desktop area.

The software is compatible with the following operating systems:

- (1) Windows NT Service Pack 4
- (2) Windows 98
- (3) Windows 2000
- (4) Windows XP (Brackett 2003, 2005;Acheson 2007a, 2007b; Barringer 2007; Busta 2007; Catlin and Kautter 2007)

CARVER is available on FDA’s Web site at <http://www.fda.gov/Food/FoodDefense/CARVER/default.htm>. The source file, carver.exe, is approximately 53.53 MB (USFDA 2005;Donald Kautter 2006;Danneels 2007; FDA 2007; News 2007; Pohl 2007; USFDA 2007c, 2008). Installation prerequisite of this program requires.NET availability on the system you are running. The auto-executable file dotnetfx.exe (22.4 MB) can be downloaded from the Microsoft Corp.’s global site and should be run prior to carver.exe

When properly installed and having chosen default settings in the Windows XP operating system, go to Start—All Program—fda—CARVER (see figure 1).

Front end window of CARVER + Shock software opens up. In the quick-start pop-up window 3 categories represent the fields namely User Assistance, Process Diagram, and Information (Figure 1).

User Assistance section has 3 tab buttons: Help, User Manual, and Tutorial. First-time users must undertake a journey to the User Manual first, which is a document file explaining in detail the theory behind CARVER + Shock software and also its technical details.

For a novice, Tutorial is of utmost help as in this section a video tutorial file teaches how to use this software in less than 5 min.

The Process Diagram section has 2 tabs: New for creating a new session and Open for opening an existing session.

The Information section has 2 tabs: Websites, clicking on it opens the link <http://www.fda.gov/Food/FoodDefense/CARVER/default.htm> in the default web browser and the other tab Contacts opens the same link (USFDA 2005; Donald Kautter 2006Danneels 2007; ; FDA 2007; News 2007; Pohl 2007; USFDA 2007c, 2008).

The main window has 3 menus on the menu bar: File, Window, and Help. This gives the software a clean look but at the same time also gives the notion to the user that this software is in the initial stages of its development as evident from the version number from the help menu.

The Window menu has 2 options, Cascade and Tile, to arrange the multiple windows opened in the program.

The File menu has options, New to create a new session, Open for opening an existing session, and Quick Start to open quick-start pop-up window. Other buttons are Edit, Delete, Export, Import, and Exit options.

Table 8–Worksheet for calculating criticality.

Entry Point	Agent	A Batch Size	B Serving Size	C Serving per Batch	D Dose Required per Serving	E Total Amount Required per Batch	F Distribution Unit	G Units Produced	H % of Units Sold Before Warning	I Units for Potential Consumption	J Consumers per Distribution Unit	K Number of Potential Exposures	L % of Units Consumed Before Warning	M No. of Exposures	N Morbidity/ Mortality Rate	O No. of Illness/ Deaths
				A/B		C*D		A/F		(H/100)*G		I*J		K*(L/100)		M/N
1.									1.							
2.									2.							

Table 9–Summary sheet for total scores for nodes across CARVER + Shock attributes.

FOOD:

TARGET (Nodes)	CRITICALITY	ACCESSIBILITY	RECOVERABILITY	VULNERABILITY	EFFECT	RECOGNIZABILITY	SCHOCK	OVERALL SCORE

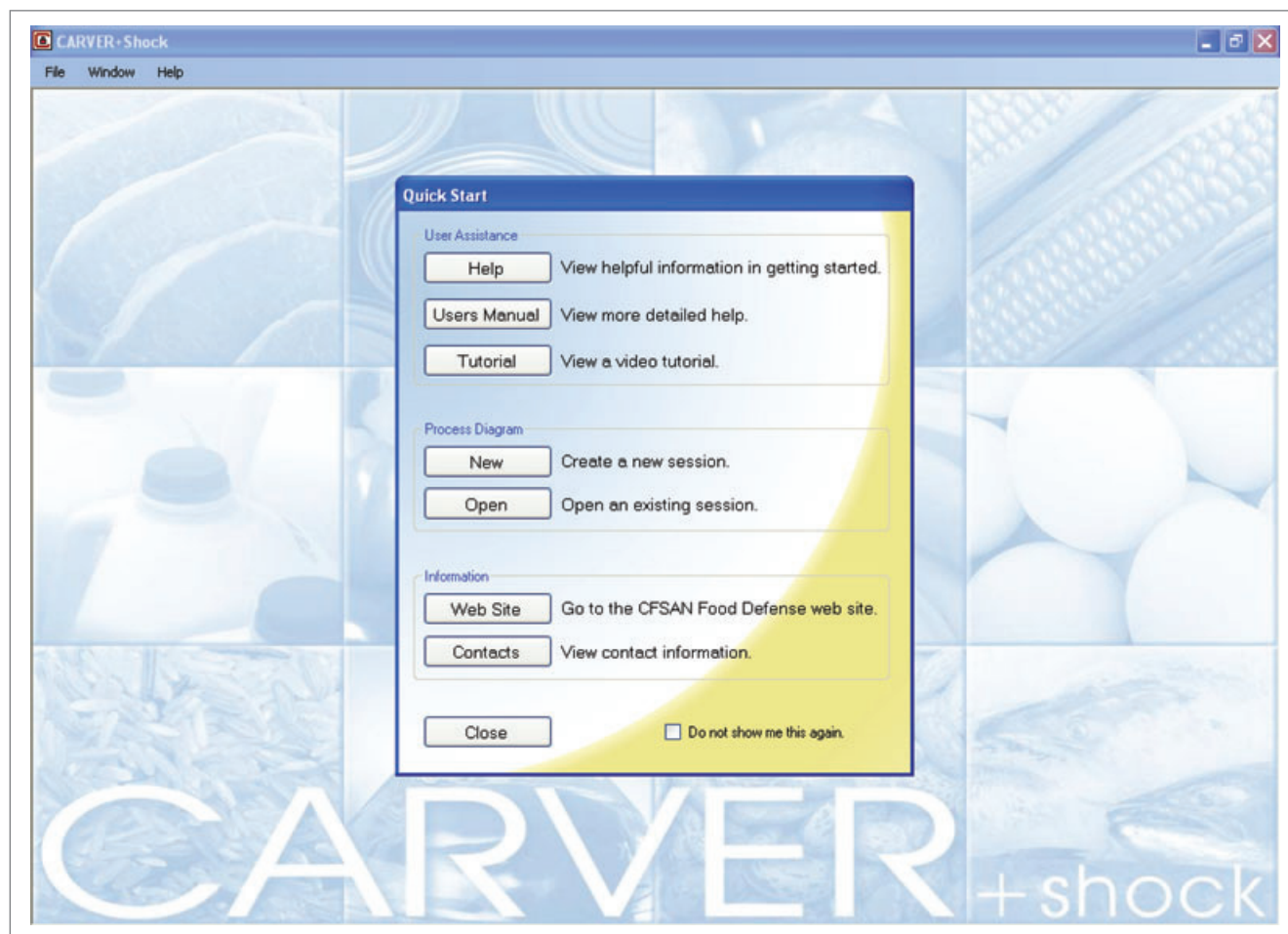


Figure 1–Start up window of CARVER + Shock.

To start with the real procedure, one must use the default templates supplied with the software available when you click on File—Open (Figure 2).

The process can be edited and used for any food industry.

CARVER + Shock Scoring Table (Individual Facilities) is given in this article and must be referred to for standard scores. This table must be taken as reference scale when designing the process diagram of any industry (see Figure 2).

CARVER + Shock software mimics the thought processes in play during a face-to-face CARVER + Shock session by having the user:

(1) Build a process flow diagram for the system to be evaluated.

(2) Answer a series of questions for each of the seven CARVER + Shock attributes for each process flow diagram node.

Each question has an associated score. Based on the answers given, the software calculates a score for each CARVER + Shock attribute and adds them up to produce a total score for each node. Analogous to a face-to-face session, total scores range from 1 to 10 for each CARVER + Shock attribute and therefore 7 to 70 for each node. The user may view the attribute scores and total for each node, the total scores for all nodes, and the attribute scores for all nodes (for example, all the node Criticality scores, Accessibility scores, and so on) (USFDA 2005; Donald Kautter

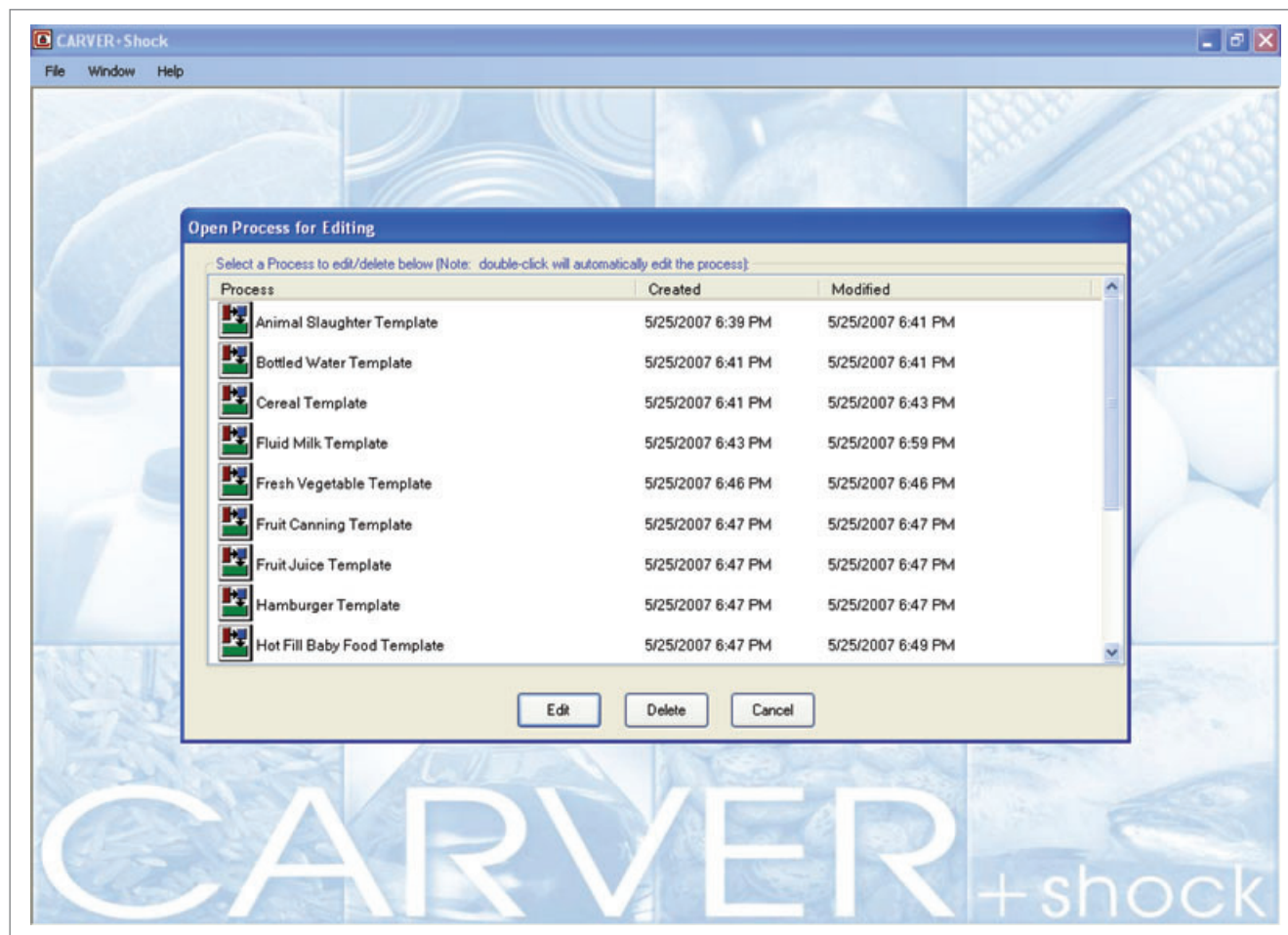


Figure 2—Templates available for usage in CARVER + Shock.

2006; Acheson 2007a; Danneels 2007; FDA 2007; News 2007; Pohl 2007; USFDA 2007a, 2007c, 2008).

Results and Discussion

Sandia is a National Nuclear Security Administration laboratory. A team from Sandia National Laboratories led the effort to computerize the FDA program so that it will be distributed as widely as possible (USFDA 2005; Keller and Killorin 2006; Rigby 2006; SPPA 2006; IFT 2007a, 2007b; SPAA 2007; Wordpress 2007a, 2007b).

This indeed is a marvelous effort by Sandia National Laboratories and FDA to start a new age of solutions for the problem, which is now in its infancy but will soon be a giant to fight against BIO-TERRORISM. The food-defense project began in longhand; in effect, in response to the federal Bioterrorism Act of 2002, which said the industry should be prepared to defend against any contingency that might arise (Brackett 2003, 2005; Donald Kautter 2006; Barringer 2007; Busta 2007; Catlin and Kautter 2007; Green 2007; Harlander 2007).

Food defense is a national and of international priority for the food industry and the government. Product developers, research and management professionals, regulators, academics, and anyone involved in food safety and quality will find this software useful to enhance their awareness of and professional development in the field (Brackett 2003, 2005; Donald Kautter 2006; Barringer 2007;

Busta 2007; Catlin and Kautter 2007; Green 2007; Harlander 2007).

The software was used and tested for ruggedness on all the platforms mentioned in the manual and was found to be quite stable as the application did not crash even a single time. So hats off to the Sandia people.

While testing, some points emerged and are mentioned here as a suggestion for improvement. These points were sent to the FDA and Sandia National Laboratories for their consideration.

- (1) File menu has options, New to create a new session, Open for opening an existing session, Quick Start to open a quick-start pop-up window. Other buttons are Edit, Delete, Export, Import, and Exit options. The compact look of this software provides a very easy impression and thus a psychological effect to the user, which is very much required when you are trying to incorporate such software in an established firm or industry that may be set in its way.
- (2) Information section has 2 tabs: Websites clicking opens the link <http://www.fda.gov/Food/FoodDefense/CARVER/default.htm> in the default web browser and the other tab Contacts opens the same link. This repetitive link could have been avoided or the Contacts tab could have been designated to some other webpage for feedback and questions pertaining to CARVER.
- (3) In the Help menu there must be an auto update link to update the patches, if any.

- (a) Apart from these preliminary findings there are some industry-specific requirements which can be met by meetings of the programmers with the industry people from time to time.
- (4) Auto save feature is missing. This feature is required in an Indian scenario as power cuts are frequent and computer systems operate mostly without UPS. So important data are lost if the person doing the data entry is too engrossed to save the document from time to time.
- (5) If the Other icon option is used, the software will only ask the questions that are asked for all nodes in that category. Because an Other process node is user-generated, there is no way to provide node-specific questions. This may affect the accuracy of CARVER + Shock scores. So when the Other icon option is to be used, then try to make the questions as elaborate and rate them as given in the reference (USFDA 2005; Wordpress 2007a, 2007b).
- (6) Because several of the algorithms used to calculate results are related, results cannot be viewed until all the questions are answered for all the icons in the process flow diagram. So utmost care is to be taken to answer all the questions and that too to the required level of accuracy (USFDA 2005, 2007a, 2007c, 2008).
- (7) To report any bug there is a form at the end of the manual. This is a good idea, but for software issues bug reporting must be done on-line. A link for bug reporting and on-line help is a must to make this software a great success.
- (8) Taking into consideration the attention span of a normal human being, 12 to 14 h of assessment are too long a period. For that a preassessment version or step must be incorporated. This would give an outline of the software and a rough estimate of the premises in question resulting in greater acceptability of this software, which is the ultimate intended goal of developing this software.

Conclusion

After the New York City attacks of 9/11, National Security has shifted to the highest priority for the United State of America and this must be top priority agenda item for every other government too. Post 9/11, everyone is looking for better ways to protect the food supply, especially from intentional contamination. Now the resources are available globally and like-minded nations are stressing collaborative efforts to fight terrorism. Bio-terrorism is at the threshold and we the people of the food industry must make up our mind to incorporate such software as CARVER + Shock in our system to be ready to avert damage or disaster. Otherwise future generations may not forgive us for the steps we could have taken but did not.

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