

Procedure

Development of HACCP protocols for the production of soy milk

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Abstract

The Hazard Analysis Critical Control Point (HACCP) protocols are aimed at ensuring the safety of food products. The system is designed to identify, prioritize and control potential problems. Such a procedure has been developed for the production of soymilk. The hazards, critical control limits, observation practices and corrective actions have been summarized in comprehensive tables. Furthermore the production process was meticulously analyzed for drafting the HACCP protocols.

Keywords: soybean, food safety, hazard, HACCP, critical limits, critical controls, India

Introduction

It is estimated that about 840 million people are undernourished and 799 million of these are from the developing countries. In India 233.3 million are reported as being undernourished, comprising about 24% of the total population. This can be combated through dietary diversity and food fortification along with supplements. In this context soybean (*Glycine max* M) with 40% protein and 20% fat assumes the most predominant position in solving the nutritional imbalances prevailing. It not only provides quality macronutrients but also various other micronutrients, which are otherwise required to fight against malnutrition. Efforts are being made to popularize various soy-based food besides the oil, which is very popular. In India about 9.3 million tons of soybean are produced annually and 80% is utilized for oil extraction. Only 10% is available for direct

food use [1]. The extruded soy chunks are very popular but too expensive and beyond the reach of common man. Among various soy food products, soymilk has great potential, as it can be prepared at domestic level using the assets available. Plain/flavoured soymilk is ready to drink and applicable to all sections of people suffering from lactose intolerance (infants/youth/old/pregnant, etc). Simple methods were developed and scaled up for its production by the investigator. Now with the introduction of food quality and safety systems HACCP has become synonymous with food safety [2, 3]. It is a world-wide recognized systematic and preventive approach that addresses biological, chemical and physical hazards through anticipation and prevention, rather than through end-product inspection and testing and thereby reducing the food-borne illness. Prior to application of HACCP the production of soy based products was according to Codex General Principles of Food Hygiene, the appropriate Codex Codes of practice and appropriate food safety legislation. Management commitment is necessary for implementation of an effective HACCP system [4]. The author has 2008a & b) developed procedures for the production of full fat soy flour and soy nuts using HACCP protocols [5, 6]. Except for this work, no relevant published data is available on the usage of HACCP in the production of soy-based food globally. Hence in the present investigation efforts were made to draft the HACCP procedures for the production of soymilk.

Materials and Methods

The soybean variety JS 335 was obtained from the Institute Farm. It was cleaned thoroughly and made free from all dirt, stubble and other foreign matter. It was stored in airtight containers until further use. Soymilk was prepared using the method developed by Gandhi *et al* [7]. AOAC [8] methods were used for analyzing various chemical constituents and APHA [9] recommended methods were used for microbiological examination of the products. All the chemicals used were of analytical grade and the experiments were conducted in triplicate and the mean values were computed for assessment. FAO/WHO [10] guidelines were used for the preparation of HACCP plans.

Results and Discussion

The soymilk was prepared with and without HACCP procedure for comparison. The detailed protocols were prepared and presented. The product description, which should be after final preparation, is given in Table 1.

Table 1. Product Description

1. Product name	Soy milk (plain/flavoured)
2. Important product characteristics of end product	$A_w < 0.5$; FFA < 1%; Total microbial counts < 50000/g. The soymilk may consist of pure water, soybean extract, sugar and salt. It has 3-4% protein, 1.5-2.0% fat and 8-10% carbohydrates. Flavored soymilk may consist of pure water, soybean extract, sugar, salt, and flavors and permitted food colors.
3. How the product is to be used	Plain/flavored milk is ready to drink and applicable to all sections of people suffering from lactose intolerance. (Infants/youth/old/pregnant etc).
4. Packaging	Plain soy milk is packed in 200/500 ml polythene bags/ glass bottles/tetra packs,
5. Shelf-life	The soymilk has shelf life of six months when packed in tetra packs or else for few weeks under refrigerated conditions. It has to be stored and distributed at ambient temperature.
6. Where the product will be sold	Retail, institutions and food service. Could be consumed as a health food.
7. Labeling instructions	Required to ensure product safety.
8. Special distribution control	No physical damage, excess humidity or temperature extremes.

The identified biological, chemical and physical hazards and the flow diagram related to the production of soymilk are shown in Table 2.

Table 2. Product ingredients and incoming material (P=physical; B=biological; C=chemical)

Raw material	Packaging material	Dry ingredients
Soybeans B, C, P	Polythene bags B, C, P	Sodium bicarbonate B, C, P
Other		
Water (municipal) B, C		

Flow diagram

Soybeans	Packaging material	Dry ingredients	Water
1. Receiving P	2.Receiving P	3. Receiving P	4. In taking
5.Storing B P	6.Storing B C P	7. Storing B C P	
8. Cleaning P	9.Inspecting B P	10. Dumping	
11. De hulling P			
12. Soaking B C			13. Chlorinating
14. Wet grinding B C			
15.Filteration B P C			
16. Homogenization B P C	17.Filling C P		
	18.Weighing B		
	19.Closing/sealing B		
	20.Inspecting B P		
	21. Labeling B		
	22. Storing B		
	23.TransportB		

B= biological; C=chemical; P=physical

Some of the unaddressed hazards connected to this process are presented in Table 3.

Table 3. Unaddressed Hazards

Unaddressed hazard from previous list	Identified methods of addressing the hazard
Soybeans could contain pesticide residues	Up stream (farm level) programs such as A: Training persons who apply pesticides. B: Purchasing registered pesticides for growers. C: Auditing growers application of pesticides and records thereof. D: Requiring periodic pesticide residual analysis reports.

The detailed HACCP plans are depicted in Table 4.

Table 4. HACCP Plan

Process step	Hazard description	Critical limits	Monitoring procedure	Deviation procedures	HACCP records
De hulling	Inefficient de hulling may cause the contamination of the product with the microorganisms.	Less than 0.1%	On line check of the sample.	Line operator to adjust the clearance of the de huller drums.	Operator log book
Blanching /cooking	In adequate heat treatment	Cook the splits as specified in the scheduled process (under pressure/open vessel boiling)	Check the quality of splits for urease test	Operator should adjust the time and temperature as per the authorized contingency plan and to inform the QC.	Operator log book.
Drying (Sun/mechanical)	Improper drying	The moisture content should be less than 8%-10%.	Check the moisture content as per the guidelines.	If moisture content is greater the splits may be dried again and inform QC	Operators log book.
Packaging and sealing	Over filling, improper gauge polythene and improper sealing	Max fill weight as specified in the scheduled process. Proper sealing leaving recommended space.	On line check to reject over and under filled bags and improperly sealed bags.	Line operator to adjust the settings.	Operators log book and quality control report.

HACCP for general activities are shown in Table 5.

Table 5. HACCP for general activities.

Stage	Activity	Control activity
Raw material harvest	Liaison with the farmers for unit operations like harvesting, threshing and winnowing.	Specifications of grain quality are required. Rejection of under sized seeds.
Raw material transport	Transport in sacks to drying area.	Correct sacking and handling.
Raw material inspection	Sampling and routine inspection.	Correct sampling methods, training and inspection methods.
Preparation of seeds	Cleaning, grading, dehulling, conditioning and blending.	Training operators for equipment, preventing insect infestations, check for moisture content.
Packaging	Filling in to containers and sealing.	Establish specifications for labels and fill weights.

Description of soymilk manufacturing process: Implementation of HACCP

Receiving soybeans (CCP-1): Soybeans must come from approved dealers. At the time of its receipt it must be accompanied with its complete quality certificate and microbiological assessment reports. The certificates should indicate the moisture content of the beans, degree of foreign materials and the microorganisms present (number of colonies), insects etc as compared to the upper approved standards of BIS/ISO. At the time of receipt, visual control of soybeans must be carried out to find out the contaminants if any. Further more the proximate composition of the beans must be established with reference to its macro and micronutrients. Defective beans mean that the soy flour will be most likely unsafe for the consumption. Soybean variety may play an important role. Bold seeded varieties are preferred.

Storage of soybeans in silos (CCP-4): The temperature (<20°C) and the relative humidity (<65%) during the storage must be low. They should be recorded at regular intervals. If any deviation from the safer limits, must be immediately rectified. When soybean is stored for a long period, microbiological analysis should be carried out.

Receiving secondary materials (greasing, detergents, insecticides, pesticides and sacs) (CCP-2): These materials must be procured from the approved suppliers with quality certificates. These materials must be suitable for using them with food items. No contamination must come from the packaging materials. If these materials do not comply with the standard specifications, must be returned to the suppliers and a new order should be placed with other suppliers.

Storage of secondary materials (CCP-3): The temperature and relative humidity during storage must be below 20°C and 65% respectively. The place should be air-conditioned. The temperature and RH should be continuously recorded and corrective actions must be undertaken whenever any deviation occurs.

Application of anti insect methods (CCP-5): Any chemicals used during storage along with the soybeans should comply with the safety legislations. The quantity should be within the prescribed concentrations.

Cleaning & grading of soybeans (CCP-6): All the physical contaminants should be removed. They should be graded. Only sound soybeans should be taken for processing. Removal of stones: The stones, metals and dust must be removed from the soybeans so that the final product will comply the quality standards as prescribed by BIS/ISO.

Weighing: the soybeans are weighed and passed through a magnetic system so that the magnetic materials are removed.

Steeping (CCP-7): As per the quality standards of water prescribed by the GFHP and food grade chemicals. The duration of soaking depends on the season. In winter long durations are required as compared with summer. In general 4-8 hours soaking may be opted. The moisture content of the soaked beans may be about 45%(wb).

Grinding (CCP-8): Type of grinders used is very critical. In general burr/colloidal/hammer mills are in vogue. The grinding may be done in two stages. Hot water may be used while grinding for inactivation of lipoxygenase, which may improve the flavor. The bean to water ratio depends on the type of milk to be prepared. In general 1:8 (w/v) is preferred for plain milks and for beverages still higher dilution factor may be considered.

Cooking (CCP-9) Pressure-cooking at 1.2kg.cm²& temperature 121°C for 40 minutes is preferred to inactivate all the anti nutritional factors.

Filtration (CCP-10): Use decanter centrifuge/rotating drum filter/batch type filters. Speed of the centrifuge or drums should be adjusted to get maximum residue separated.

Homogenization (CCP-11): Thorough mixing of the oil/emulsifier as per the required quantity before homogenization. Homogenize at 3500 psi for 30 minutes. Standardization of soymilk base by adding ingredients like sugar syrup, water, flavors (flavored milk) may also be done during this process.

UHT/pasteurization (CCP-11): Treatment of soymilk in UHT plant or direct pasteurization.

Packaging (CCP-12): During packaging the milk can possibly be contaminated with the microorganisms causing quality deterioration. Hermetic sealing and upright position of the packaging material can avoid this. There should not be any migration of the low molecular weight substances from the packages. Further more contamination can take place from foreign materials like insects and rodents that accidentally happen to be packed with the milk. The personnel should comply with the (Good Manufacturing Process).

Containers

Food Processor:

- + Reliable supply of packaging material.
- + Low fixed cost per unit.
- + Low energy consumption.
- + Packaging should keep product quality.
- + Service and spare parts availability.
- + Space saving in storage/ minimum refrigeration.

Distributor:

- + Light weight.
- + Effective space utilization.
- + Minimum refrigeration.
- + Labour saving transport packaging.
- + Withstand rough handling.

Retailer:

- + Minimum refrigeration space.
- + Attractive packaging with sales appeal.
- + Minimized handling of empties and transport packaging.

Containers:

- + Convenient size.
- + Safe, easy to handle, drink and pour from.
- + Retain product quality.
- + Easy to dispose off.
- + Have high image/ novelty.

- ✚ Product identification.

Kinds of packages:

- Returnable: usually for refrigerated distribution with in limited area.
- One-way: used for refrigerated (pasteurized) products distribution with in a limited area/ non refrigerated (UHT/sterilized) products for short and long distance distribution.

Choice of container depends on the following factors:

- Desired retail price of the product.
- Product quality protection practices.
- Desired image.
- Refrigerated or non-refrigerated distribution.
- Type of distribution vehicle.
- Type of transport container available.
- Service of filling machine.
- Packaging size.
- Means of opening package.
- How to drink from or pour from container.
- Place of consumption.
- Fixed cost of equipment.
- Labeling possibilities.
- Novelty factor.

The pasteurized product (75°C for 15 sec) can be filled in cartons, plastic bags, glass or plastic bottles. The product should be stored under refrigeration and has then a shelf life of approximately one week. The UHT treated product (140°C for 4 sec) should be aseptically packed in cartons, plastic bags or plastic bottle. The shelf life is up to several months in ambient temperature. No preservatives are involved. It provides adequate shelf life and a product with good flavor and nutritional value. In bottle/can, sterilized soy milk (120°C for 20 min) has the longest shelf life but is also a less nutritious product. Taste and appearance are also affected.

Crate/outer box/transport container: The outer container in which the individual packages or bottles are stored and transported should be considered early on in the planning of a suitable packaging system.

Some factors to keep in mind are:

- Returnable or one-way container.
- Degree of automation.
- Degree of protection against physical impact, dust, rain, sunlight, theft and stacking height.
- Ease of handling in plant, storage, trucks and shops.
- Bulkiness/weight.
- Cost per volume of soymilk transported.
- Durability.
- Desirability of non-authorized uses.
- Function as sales unit in shops.

Types of containers and what they are suitable for are given Table 6.

Table 6. Different containers recommended

	Returnable	One way	For Pasteurized product	For UHT treated aseptic packed product	For sterilized product
Primary Container					
Glass bottle	*	*	*	*	*
Plastic bottle		*	*	*	*
Plastic bag		*	*	*	*
Carton		*	*	*	
Can		*			*
Transport Container					
Wooden grate	*				
Plastic crate	*				
Cardboard box		*			
Cardboard tray/shrink film		*			
Wrap around box		*			

Metal detector (CCP-13): The packed product passes through a metal detector. The product is then checked for its weight and placed in boxes (secondary packaging). The boxes are placed on the pallets and the packets are wrapped with film.

Storage of soy milk (CCP-14): The storage temperature and relative humidity must be below 20°C and 65% respectively. The place should be air-conditioned. Both the temperature and relative humidity must be recorded regularly and corrective actions must be undertaken whenever deviation occurs.

The expected quality of soymilk is given in Table 7.

Table 7. Quality of soymilk expected (Nutritional values per 100 g)

Parameter	Value
Protein:	a maximum of 4.0g
Fat:	a maximum of 2.0g
Carbohydrates:	a minimum of 3.0g
KJ:	204
Kcal:	49
Cholesterol:	0
Lactose:	0
SF:	15%
PUFA:	63.5%
MUFA:	1.5%
Crude Fiber:	a maximum of 4%
Ash:	a maximum of 6.5%
Moisture:	a maximum of 80%
Microbiology:	
Total plate count:	20,000/g maximum
Total coli forms:	100/10g maximum
<i>Salmonella</i> :	Negative/100g
<i>E.coli</i> :	Negative/100g
<i>Staphylococcus</i> :	100/10g maximum
Yeast:	100/10g maximum
Mold:	100/10g maximum.
Antinutritional factors	
TI	less than 75% of original.
Urease activity:	Nil
Available lysine:	Min 5.5g/6g N
Sensory parameters:	
Color:	Creamy to yellow
Odor:	Less beany
Taste:	Nutty
Defects:	
Insect parts:	Total absence.
Foreign material:	Total absence.
Black specks:	Total absence

The soymilk was produced with and without HACCP and the results are presented in Table 8.

Table 8. Quality assessment of the soy milk

Quality standard expected	With out HACCP	With HACCP
Composition:		
Protein: a maximum of 4%	3.2%	4.3%
Fat: a maximum of 2%	1.6%	2.0%
Carbohydrates a maximum of 3%	2.2%	3.0%
Crude Fibre: a maximum of 4%	5.0%	3.7%
Ash: a maximum of 6.5%	4.4%	3.3%
Moisture: a maximum of 80%	80%	80%
Microbiology:		
Total plate count: 20,000/g max	30,000/g	6,000/g
Total coli forms: 100/10g max	130/10g	Nil
<i>Salmonella</i> : Negative/100g	20/100g	Negative
<i>E.coli</i> : Negative/100g	15/100g	Negative
<i>Staphylococcus</i> : 100/10g maximum	135/10g	Nil
Yeast: 100/10g maximum	100/10g	Nil
Mold: 100/10g max.	112/10g	Nil
TI: less than 75% of original.	<50%	<80%
Urease activity: Nil		
Available lysine: Min 5.5g/6g N	Nil	Nil
Sensory parameters:	5.2g/6gN	5.6g/6gN
Color: Creamy to yellow		
Odor: Less beany	Yellow	Creamy
Taste: Nutty	Beany	Less beany
Defects:	Nutty	Nutty
Insect parts: Total absence.		
Foreign material: Total absence.	Absent	Absent
	Absent	Absent

The synoptical presentation of HACCP is shown in Table 9.

Table 9. Synoptical presentation of hazards, CC limits, observation procedures, monitoring and corrective measures for production of soymilk.

Process step	Hazard description	Critical limit	Observation procedures		Responsible	Monitoring procedures	Corrective actions
			Control CCP	Frequency			
Receiving of soybeans (CCP-1)	Presence of foreign matter in soybean (P) Growth of micro organisms (B) Insects Fungi	5% Absence Out of five samples two of them 10^2 - 10^4 cfu/g, Humidity <13% Protein: 38-40% Other quality parameters as per standards.	Visual control of sample/control of the certification per lot. Control of the certification.	Per lot	QAM	Control of specifications and provide quality certificates from suppliers.	Rejection of lot and or change the suppliers.
Receiving of secondary materials (greasing agent, detergents, insecticides, pesticides, sacks etc (CCP-2)	Chemical substances migrating from secondary materials.	Materials suitable for food contact.	Control of the certification.	Per lot	QAM	Control of specifications and provide quality certificates from suppliers.	Rejection of lot and or change the suppliers.
Receiving of packaging materials (CCP-3)	Low molecular weight compounds migrating from packaging materials.	No migration.	Control of specifications.	Per lot.	QAM	Observations of the specifications and supply quality certifications from the suppliers. Evaluation of the suppliers.	Rejection of the lot and/or change of the supplier.
Water	Total coli forms (B)	In agreement with the community legislation	Lab control of water quality.	Monthly.	QAM	“	“

	<p>Feces Coli forms (B)</p> <p>Feces Streptococcus (B)</p> <p>Sulphur reducing Clostridium (B)</p> <p>Presence of undesirable and toxic substances in water (e.g. Heavy metals, ammonia, hydrocarbons, parasites, nitrate).</p> <p>Excessive quantity of residual chlorine[©],</p> <p>Presence of foreign materials (P).</p>	<p>80/778 for potable water.</p> <p>“</p> <p>“</p> <p>“</p> <p>“</p> <p>“</p>	<p>“</p> <p>“</p> <p>“</p> <p>“</p> <p>“</p>	<p>“</p> <p>“</p> <p>“</p> <p>“</p> <p>“</p>	<p>“</p> <p>“</p> <p>“</p> <p>“</p> <p>“</p>	<p>“</p> <p>“</p> <p>“</p> <p>“</p> <p>“</p>	<p>“</p> <p>“</p> <p>“</p> <p>“</p> <p>“</p>
Storage of soybeans in silos (CCP 4)	<p>Growth of micro organisms (B) & insects.</p> <p>Fungi (B)</p>	<p>Absence</p> <p>In five sample two of them 10^2-10^4 cfu/g. Humidity < 13% Temp: < 25°C Air Conditioning.</p>	<p>Quality control</p> <p>Monitoring and recording the humidity and temperature.</p>	<p>Per lot</p> <p>Daily</p>	<p>QAM</p> <p>QAM</p>	<p>Control of specifications.</p> <p>“</p>	<p>Rejection of lot unsuitable.</p> <p>“</p>
Steeping (CCP-5)	<p>Quality of water & chemicals used.</p> <p>Steeping time and temperature of the water</p>	<p>As per the quality standards of water prescribed by the GFHP and food grade chemicals. Set them as described in the process.</p>	<p>Inspection of the quality certifications</p> <p>Recording of temperature and timings.</p>	<p>Per lot</p> <p>Per lot</p>	<p>Production Manager</p> <p>Production Manager</p>	<p>Control of specifications.</p> <p>Control of conditions as per the season.</p>	<p>Rejection of lot unsuitable.</p> <p>Repair and maintenance of the equipment and rejection of lot if not properly steeped.</p>

Grinding (CCP-6)	Type of grinder: burr/colloidal/hammer mills Addition of hot water if required.	Highly efficient grinding systems and in two stages.	Inspection of the quality of the mash and determine the TSS.	Per lot	Quality Testing personnel	As per the prescribed standards.	Adjustments of the grinding systems to get the desired particle size prior to operation, otherwise replace the units.
Cooking (CCP-7)	Pressure cooking at 1.2kg.cm ² & temperature 121°C for 40 minutes	Precise control of pressure, temperature and holding time.	Inspection of the cooking systems and recording the parameters.	Per batch	Production Manager	Control of conditions.	Maintenance of the systems prior to use and repair in case required, otherwise replace them.
Filtration and deodorization (CCP-8)	Use decanter centrifuge/rotating drum filter/batch type filters. Deodorization under vacuum	Speed of the centrifuge or drums should be adjusted to get maximum residue separated. Monitoring the vacuum and inspection of the quality of the extract.	Inspection of the units. Control the vacuum and recording the data.	Every run Per lot	Production Manager Production Manager	Control of conditions. Control of conditions	Maintenance of the systems prior to use and repair in case required, otherwise replace them.
Addition of additives (CCP-9)	Standardization of soymilk base by adding ingredients like sugar syrup, water, flavors (flavored milk).	All the dry ingredients must be of food grade.	Control of quality specifications of the ingredients and concentrations to be used for standardization. The exact composition of the product must be controlled.	Per batch	QAM	Observations of the specifications and supply quality certifications from the suppliers. Evaluation of the suppliers	Rejection of lot and or change the suppliers.
Homogenization (CCP-10)	Use of good quality vegetable oil/emulsifier.	Thorough mixing of the oil/emulsifier as per the required	Control of specifications.	Per lot	Production Manager	Observations of the specifications and supply quality	Prior maintenance of the system

		quantity before homogenization. Homogenize at 3500 psi for 30 minutes.				certifications from the suppliers. Evaluation of the suppliers. Recording the pressure of the homogenizer and time of holding.	
UHT/Pasteurization (CCP-11)	Treatment of soymilk in UHT plant or direct pasteurization.	Control of steam and temperature.	Good quality instruments fitted with the systems for recording	Per lot	Production Manager	Evaluation of the units regularly.	Maintenance of the units.
Weighing	Correct weighing measures as required	Control of weights.	Weighing scales or automatic weighing and filling units must be inspected for their accurate weights.	Per batch	Production Manager	Evaluation of the units regularly.	Maintenance of the units.
Aseptic filling (CCP-12)	Filling in aseptic containers.	Quality containers meeting the specifications.	The quality must be verified.	Per Batch	QAM	Observations of the specifications and supply quality certifications from the suppliers. Evaluation of the suppliers	Rejection of lot and or change the suppliers.
Storage (CCP-13)	Control of temperature and RH	Temperature < 20°C RH < 65%	Temperature and RH should be regularly tested. AC unit must be checked regularly for its functioning.	Every half an hour.	Production Manager	Precautionary maintenance of air conditioning unit.	Rejection of the doubtful lot.
Transportation	GMP&GFHP	Vehicle for food transport.	Use anti insect methods and disinfection of the vehicle regularly for maintaining GFHPs.	Per lot	Production Manager	Precautionary maintenance of the vehicle.	Rejection of the lot if not maintains the quality as required by the food laws.
Cleaning in Place	Automatic/manual cleaning of pipe	CIP plant must be SS and	Use the set practices like: Pre rinse with water,			Must be of best SS and	

	lines, tanks etc.	consists of tanks for water, lye & acid, disinfectant dosing system, SS centrifugal pump, SS air operated valves and steam heating system.	rinsing with lye,70°C, flushing with water, rinsing with acid 70°C, flushing with water and finally disinfection with disinfectant.			other equipment from reputed Dealers	
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Thus the results indicate the importance the HACCP for producing safe and quality soymilk.

Conclusion

HACCP procedures were developed for making soymilk with utmost quality and safety for use. A proactive approach was suggested for controlling the hazards throughout the supply chain of soymilk production. More flexibility in addressing identified hazards is given in the proposed HACCP program, which permits the soymilk processors to select the appropriate and economical methods of control. Quality control managers are responsible for the design and maintenance of the suggested protocols with government agencies auditing compliance. It will have great export potential and domestic utilization.

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